

# 2022 ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

# **GENOR BIOPHARMA HOLDINGS LIMITED**

(Incorporated in the Cayman Islands with limited liability)

Stock Code: 6998



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# **About this Report**

Genor Biopharma Holdings Limited (together with its subsidiaries hereinafter referred to as "the Group", "Genor") has prepared this 2022 Environmental, Social and Governance ("ESG") Report in accordance with the Environmental, Social and Governance Reporting Guide (the "Reporting Guide"), which is contained in Appendix 27 to the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited as stipulated by The Stock Exchange of Hong Kong Limited ("SEHK"). This report follows the reporting principles of Materiality, Quantitative and Consistency as well as the Reporting Boundary in respect of collecting relevant materials, analysing data and reviewing information over the course of its preparation and compilation.

#### **Reporting Period and Boundary**

This report focuses on the Group's ESG policies and initiatives from 1 January 2022 to 31 December 2022 (the "Reporting Period"). Unless otherwise specified, the report cover the Group's principal operating entities during the Reporting Period, including Genor Biopharma Co., Ltd. ("Genor Biopharma"), Yuxi Genor Biotechnology Co., Ltd. ("Yuxi Genor") and the San Francisco-based Ab Therapeutics ("ABT"). The information and data in this report are consistent with the scope of the Group's financial report.

#### Data and Information Sources

The information in this report comes from the Group's public information, internal policies, statistics, reports and records.

#### **Reliability Assurance**

This report was reviewed by the management and approved by the Board of Directors on 30 March 2023. The Group is responsible for the authenticity, accuracy and completeness of the content in this ESG report.

This report is published in both traditional Chinese and English. Should there be any discrepancy, the traditional Chinese version shall prevail. In case of any conflict or inconsistency between this report and the Group's 2022 Annual Report, the Annual Report shall prevail.

#### **Publish and Access**

The Report is published on the HKEXnews website of the Hong Kong Exchanges and Clearing Limited (www.hkexnews.hk) and the website of the Company (https://www.genorbio.com/) for reading and downloading.





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# Message from Chairman of the Board and CEO

2022 was a year of volatility and unprecedented challenges. In view of the uncertainties brought by the pandemic and lasting geopolitical impact, a large number of industries including biopharma are confronted with multifaceted risks. While responding to these challenges, Genor crystalised its targets and strategy in light of much deliberation over both internal and external environment, and is committed to turning what is critically unfavourable into opportunities.

On 10 May 2022, the National Development and Reform Commission issued the "14th Five-Year Plan for the Development of Bioeconomy", China's first five-year plan for biopharma sector highlighting specific deliverables. Biopharma has been listed as one of the core competences for building an innovation-driven country, and is essential for China to secure a strong foothold in the global high-tech scene. As an innovation-driven biotech company, Genor is gratified to have taken part in the rapid growth of the industry, whereby it fortifies a business model that is rooted in China with global reach and featured by innovation.

It is expected that between 2025 and 2030, a quarter of China's population will be seniors over the age of 60. As living standards and knowledge levels increase, the demand for high quality healthcare is rising. We acknowledge the growing demand for medical treatment in the context of an increasingly aging population. With the mission of "Providing Innovative Therapeutics Initially for Patients in China and Gradually for Patients Globally", we are committed to leveraging our expertise to develop more innovative products, and enhancing the accessibility of high-quality innovative drugs by facilitating clinical programs and quality manufacturing.

We understand that strengthening corporate governance and risk management are the cornerstones to ensure the sustainable and rapid development of Genor in a changing environment. By upholding the strategy emphasising "Focus, Optimisation and Acceleration", Genor has consistently focused on therapeutic areas that have large unmet medical needs in oncology, immunological and other diseases, and has implemented efficient operational systems in R&D, CMC, clinical and manufacturing to ensure drug safety and efficacy, as well as continue to enhance accessibility of its products.

Thanks to the successful establishment of highly differentiated T-cell Engager (TCE), immuno-oncology bispecific/multi-specific antibodies and Antibody-Drug Conjugate (ADC) R&D platforms, Genor dedicates itself to products with first-in-class ("FIC") and best-in-class ("BIC") potential globally, and conducts molecular research with great potential to produce clinically effective and commercially viable drugs.

In terms of Investigational New Drug ("IND") filing and the facilitation of clinical trials, the R&D team fully evaluates and studies the preclinical pharmacology and toxicology to support IND filing; CMC continuously optimises the technical advantages of process development; the clinical development team works with top-notch clinical experts to develop clinical development



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**Dr**. **GUO Feng** Chairman of the Board and CEO

strategies that maximise the value of the products, and roll out science-based clinical trial plans to facilitate efficient implementation; the regulatory affairs team collaborates with various departments to complete IND filings in accordance with the regulatory requirements in China and Australia, and communicates with drug evaluation authorities regularly. All the efforts mentioned above form the solid foundation that ultimately enables optimal clinical trial design, rapid filings and approvals.

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With an in-depth understanding of product science and relevant mechanisms, as well as the efficient and thorough coordination among departments. Genor overcame multiple challenges derived from the COVID 19 pandemic. We advanced several clinical trials at an above-industry average rate, including GB491 (Lerociclib), GB261 (CD20/CD3, bispecific antibody or BsAb) and GB263T (EGFR/cMET/cMET, trispecific antibody or TsAb), and won approval for the commercialisation of Jiayoujian 佳佑健® (GB242, Infliximab).

While valuing efficiency, the Group considers drug efficacy and safety unwavering priority. Our efficient and compliant guality management system covers all aspects of our business operations, including R&D, pharmaceutical process technology, manufacturing and management. As we continue to improve CMC quality control, quality research platform and MAH-related quality systems, we have also developed and implemented multiple management protocols in clinical research, material supply, drug manufacturing guality and supplier management, which provide strong support for rigorous guality management and drug efficacy management under different projects, scenarios and processes.

All these initiatives are made possible thanks to the professional execution and seamless collaboration across departments, as well as team's passion for innovation. In addition to optimising corporate structure in 2022, Genor also created platforms to engage employees whose collective enterprising spirit, high morale and sense of responsibility are treasured to power the company in the next stage of development.

Genor pays close attention to its impact on environment and the efficiency of resource use to reduce carbon emissions in its business operations. Combating climate change is highly compatible with our development goals. Our R&D centre in Zhangjiang, Shanghai, and the GMP commercial manufacturing site in Yuxi, Yunnan province regulate the use of facilities and operations in all activities including inspection, manufacturing and transportation, in the hope of reducing energy consumption and use of resources, and encouraging every employee to participate in daily energy-saving actions.

We are honored to be awarded the "Top 30 Innovative Antibody Drug Companies in China" and "Top 100 Innovative Pharmaceutical Companies in China 2022", which represents the recognition of Genor's persistence in innovation, sustainable development and corporate responsibility in this special year. With the recovery of different sectors in 2023, Genor is highly motivated to deliver high-quality growth. With clear goals and strategies, the Group aspires to unleash its potential and fulfill its vision and mission with accelerated independent innovation and global reach.

"Genor aspires to become a biopharmaceutical company with global presence, serving patients and society."



# Environmental, Social and Governance Strategy

# **Group Overview**

Genor focuses on therapeutic areas with substantial unmet medical needs in oncology, immunological and other disease areas, and is committed to building an innovation-driven and platform-oriented biotech company that encompasses early drug discovery, preclinical research, clinical development, CMC development and commercial manufacturing capabilities.

We believe that everyone deserves to enjoy good health and has access to safe and effective treatments when he or she falls ill. With a wealth of more than 15 years of experience in China, we operate with high standards in medical and business ethics and have remained steadfast in our business proposition of benefiting patients through a highly differentiated R&D pipeline. Moreover, we leverage our FIC and BIC product development capabilities, advanced pharmaceutical processes, industryleading clinical development efficiency, cost effectiveness, safety- and efficacy-driven quality management, and professional partnerships forged to enhance the accessibility and affordability of innovative medicines, so as to address the unmet medical and healthcare needs of patients in China and around the world.

We respect every employee, and have created a working environment that encourages our staff to break new grounds and take up challenges. It is a place where they can integrate their personal career planning with the prospect of Genor, driving shared development and growth. Together in this process, we join hands with our partners to help patients and fortify our enterprise values. Our Mission is to become a biopharmaceutical engine in discovery, research, development, manufacturing and commercialisation of innovative therapeutics initially for patients in China and gradually for patients globally.

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# **2022 Highlights**

# "Focus, Optimisation and Acceleration" as Core Strategy

#### Accelerate Key Clinical Projects

#### GB491 (Lerociclib, Differentiated oral CDK4/6 inhibitor)

 In January 2022, the first patient in Phase III clinical trials of GB491 (Lerociclib) in combination with Letrozole in the first line treatment of HR+/HER2- advanced breast cancer was dosed.

#### GB261 (CD20/CD3, BsAb)

- Efficacy has been observed in GB261 (CD20/CD3, BsAb)'s first-in-human (FIH) clinical trial in Australia in the dose escalation low-dose group with preliminary clinical Proof of Concept (POC) data, which was consistent with the molecular design mechanism of GB261, indicating a good safety, pharmacokinetic profile and clinical antitumor activities. The high-dose group currently is in process.
- On 23 May 2022, GB261 (CD20/CD3, BsAb) obtained an implied license for Phase I/II clinical trials from the National Medical Products Administration ("NMPA") for the treatment of patients with recurrent or refractory B-cell non-Hodgkin lymphoma (B-NHL) and chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL).
- On 8 September 2022, GB261 (CD20/CD3, BsAb) Phase I/II clinical trials achieved the first patient dosing in China.

#### GB263T (EGFR/cMET/cMET, TsAb)

- On 18 May 2022, GB263T (EGFR/cMET/cMET, TsAb) FIH clinical trial achieved the first patient dosing in Australia, which is for the treatment of patients with advanced non-small cell lung cancer (NSCLC).
- On 2 June 2022, the clinical trial application for GB263T (EGFR/cMET/cMET, TsAb) was approved by NMPA to commence Phase I/II clinical trials for the treatment of patients with advanced NSCLC.
- On 14 October 2022, GB263T (EGFR/cMET/cMET, TsAb) Phase I/II clinical trials achieved the first patient dosing in China. The high-dose group currently is in process.

#### GB492 (STING agonist)

- In January 2022, approval was obtained from the CDE to directly conduct a doseescalating study of GB492 (IMSA101) in combination with PD-1 in patients with advanced malignancy. Monotherapy clinical trials were finished and a dose escalation up to 400ug was completed in January 2022
- In this clinical trial, an innovative FIH trial design was employed to combine the dose escalations when GB492 (IMSA101) is administered alone and when it is administered with Aibining<sup>®</sup> 艾比寧<sup>®</sup>(GB226, Geptanolimab). It is the first STING agonist combination therapy that has obtained clinical trial approval in China.

#### Jiayoujian 佳佑健<sup>®</sup> (GB242, Infliximab) received new drug application (NDA) approval

 On 23 February 2022, the NMPA granted NDA approval for Jiayoujian 佳佑健<sup>®</sup> (GB242, Infliximab) which is used for the treatment of rheumatoid arthritis, ankylosing spondylitis, psoriasis, adult ulcerative colitis, adult and pediatric (aged above 6 years old) Crohn's disease and fistulizing Crohn's disease.



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#### Explore Strategic Collaborations

Cooperative Development Agreement with Abogen Biosciences (Abogen)

In May 2022, the Group entered into a cooperative development agreement • with Abogen to jointly develop globally innovative mRNA products and related pharmaceuticals, and research and develop mRNA drugs for tumor treatment.

#### Focus on Highly Differentiated Innovation

- The R&D team focused on developing targeted antibodies and projects with FIC/BIC potential and continue to promote the research and development platform for discovering T-cell Engager, bi-specific/multi-specific in immuneonology and BsADC.
- As of December 2022, five FIC/BIC bi-specific/multi-specific antibody projects were carried out and nearly 10 differentiated innovation projects involving different molecular forms were in the early stage of research and development.

#### **Optimise and Enhance Efficiency to Tackle Challenges**

- Focus on priority pipelines, reduce non-essential expenses and take proactive measures to enhance operational efficiency.
- As one of the main biotech companies in the Shanghai Zhangjiang Hightech Park, we were among the second batch of companies in the list to resume operation as published by the Shanghai municipal government on 28 April 2022. Our resumption of work and manufacturing ensured that the key projects are on track.



# **Honours**



On 16 September 2022, Genor was re-elected as "Top 30 Innovative Antibody Drug Companies in China" in the 2021 China Top 100 Biopharmaceutical Enterprise Innovation List series.



In December 2022. Genor was nominated for the 2021-2022 CHIP Award, and was selected as one of the 36 outstanding innovative projects that serve both social and economic values in China's healthcare sector.



In December 2022, Genor was included in the "Top 100 China Pharmaceutical R&D Strength Ranking 2022" list, being an innovative player in China's domestic pharmaceutical industry.

# **ESG Governance**

# Materiality Assessment and Confirmation

#### Stakeholder Engagement

Genor follows an important principle of identifying material ESG topics for this reporting. We engage with stakeholders through various means and listen to their opinions and feedback in daily business activities. We respond to their expectations balancing competing priorities for the Group's sustainable development. These stakeholders include but not limited to government and regulatory bodies, investors, employees, suppliers and partners.



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Stakeholder	Topics of Interest	Communication and Respons
Shareholders and Investors	<ul> <li>Economic Efficiency</li> <li>Compliance</li> <li>Improve Corporate Governance</li> <li>Transparency in Information Disclosure</li> <li>Progress of R&amp;D Pipeline and Clinical Projects</li> <li>Globalisation Strategy</li> </ul>	<ul> <li>Shareholder Meetings</li> <li>Investor Meetings and Roadshows</li> <li>Industry Summits</li> <li>Press Releases and Announcements</li> <li>Company Website Announcements</li> <li>Annual and Interim Reports</li> </ul>
Government and Regulatory Authorities	<ul> <li>Compliance</li> <li>Transparency in Information Disclosure</li> <li>Quality and Safety of Medicine and Services</li> <li>Patient Rights and Privacy Protection</li> <li>GHG Emissions and Management</li> <li>Pollutant Emissions and Management</li> </ul>	<ul> <li>Government – Enterprise Meetings</li> <li>Seminars</li> <li>Compliance Reports</li> <li>Regular Information Disclosure</li> <li>Implementation of Relevant Environmental and Emission Management Policies</li> </ul>
Customers (Hospitals, Pharmacies and Patients)	<ul> <li>Innovative Discovery and Clinical Pipeline Programs</li> <li>Drug Indications, Efficacy, Quality and Safety</li> <li>Intellectual Property Rights Protection</li> <li>Subject Privacy Protection</li> </ul>	<ul> <li>Drug Efficacy Disclosure and Communication</li> <li>Customer Satisfaction</li> <li>Customer Grievance Mechanism</li> <li>Medication Instructions</li> </ul>
Employees	<ul> <li>Employee Rights</li> <li>Occupational Health and Safety</li> <li>Development and Training</li> <li>Compensation and Benefits</li> <li>Code of Conduct</li> </ul>	<ul> <li>Cultivation of Corporate Culture</li> <li>Trade Union and Team Building Activities</li> <li>Employee Communication Mechanism</li> <li>Staff Meetings</li> <li>Employee Training</li> <li>Employee Equity Incentive Program</li> </ul>
Suppliers and Other Partners	<ul> <li>Sustainable Supply Chain Management</li> <li>Procurement Management</li> <li>Partner Compliance</li> <li>Resource Utilisation and Use Efficiency</li> <li>Intellectual Property Rights Protection</li> </ul>	<ul> <li>Supplier Introduction, Evaluation and Audit Mechanism</li> <li>Procurement Management</li> <li>Work Meetings</li> <li>Annual Audit</li> <li>Industry Summits</li> </ul>
Public and Media	<ul> <li>Health Literacy</li> <li>Hazardous Waste Disposal and Management</li> </ul>	<ul> <li>Press Releases and Announcements</li> <li>Media Activities</li> <li>Charity and Social Events</li> <li>Industry Summits</li> </ul>
Industry Association and other NGOs	<ul> <li>Quality and Safety of Products and Services</li> <li>Compliance</li> <li>Hazardous Waste Disposal and Management</li> <li>Industry Collaboration and Development</li> </ul>	<ul> <li>Industry Exhibition and Discussion</li> <li>Company Website Information Releases</li> <li>Company Reports</li> </ul>

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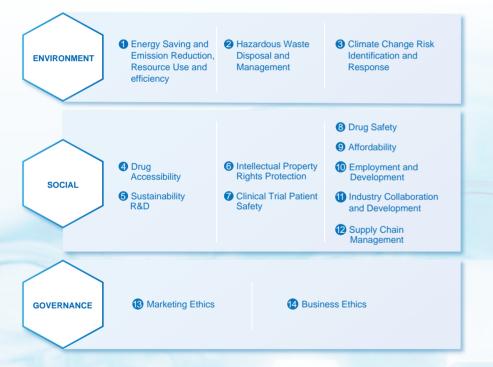
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#### Materiality Assessment and Prioritisation

In 2022, the Group continued to communicate with stakeholders and identified the Group's material topics by taking into account the material topics of the Biotechnology and Pharmaceuticals Sector under Sustainability Accounting Standards Board (SASB), the Group's materiality matrix for 2021, and industry best practices in sustainability disclosure. The material topics of the year include three environmental, nine social and two governance issues.



In accordance with the relevant requirements of Appendix 27 to the Rules Governing the Listing of Securities on the SEHK, the Group herein confirmed that the materiality matrix for 2022 is formed drawing from the materiality of topics to the stakeholders and the impact to economy, environment and society. The most important material topics are drug accessibility, sustainable R&D, clinical trial patient safety, drug safety and affordability.

#### GENOR 2022 MATERIALITY MATRIX



The materiality matrix and ranking of material topics above were submitted to the Board and approved on 30 March 2023. The remainder of this report will be presented based on these topics among other disclosures.



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**Board Statement** 

The Board understands that sustainability is of profound importance to the development of our business and the industry we are in, as well as the well-being of humankind. Good corporate governance is at the heart of the Group's sustainable development and value creation. We will, therefore, continue to elevate our governance standards to ensure that sustainability is integrated in our management and action plans whereby the expectations and concerns of the stakeholders are duly addressed.

As the highest decision-making body on sustainability, the Board of Genor oversees corporate sustainability strategy, risk management and disclosure. It is also responsible for managing and tracking the progress of ESG targets and material topics. In the best interest of the company, the Board incorporates sustainability in its decision-making process.

Genor attaches great importance to the uncertainty that climate change brings to humans. To strengthen the Group's adaptability, we are incorporating climate-related risks into the overall risk assessment and management system. The board continues to oversee the Group's progress in energy management, conservation and emissions reduction as well as identification and evaluation of climate risks, and discusses them as specific topics when appropriate.

The Group continues to explore and review sustainable development goals that fit for its current stage of development. Due to business and organisational optimisation during the Reporting Period, the intensity indicators of several ESG KPIs were weakened on the back of an evident drop of average number of employees for the year. Nevertheless, we are actively exploring more appropriate method for intensity calculation and considering the feasibility of setting medium-term sustainability goals.

## **Compliance Management**

Genor complies with the *Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited*, and the applicable laws and regulations where it operates. As we continue to strengthen corporate governance, we strive to regulate corporate conduct to a higher standard in addition to compliance. With a firm belief in business integrity, we emphasis compliance management and risk management to facilitate the Group's sustainable development. During the Reporting Period, we provided trainings to cultivate awareness of compliance and business ethics for new joiners among all staff.

The Group strictly complies with relevant national laws and regulations, including the *Company Law of the People's Republic of China*, the *Securities Law of the People's Republic of China*, the *Anti-unfair Competition Law of the People's Republic of China*, the *Anti-money Laundering Law of the People's Republic of China* and the *Industry Anti-corruption Regulations*, and has developed relevant internal policies and systems. Both our Internal Control Department and Compliance Department conduct regular inspections on the implementation and risk management of the systems. During the Reporting Period, based on the available information, no petitions against corruption and other forms of misconduct were received and no related lawsuits were in progress.

#### Anti-corruption Training

To continue to deepen employees' understanding on compliance and anti-corruption policies, the Group requires all to attend online trainings every year and organises special online trainings on anti-corruption for new joiners. At the same time, the Group's Directors of the Board are required to attend routine anti-corruption trainings. In 2022, the Group offered training sessions to all on anti-corruption, anti-bribery, information security and intellectual property rights protection.

Genor requires all staff to sign an *Anti-bribery and Anti-corruption Pledge*, each acknowledging that he or she is aware of and will comply with relevant laws and regulations. Performances related to anti-bribery and anti-corruption are set among key performance indicators and are included in performance appraisals to regulate and guide compliance behavior. We also require our suppliers, distributors and other business partners to follow the same principles.



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#### Whistleblowing Policy

The Group has laid down a *Whistleblowing Management Policy* to build awareness and related mechanism against potential corruption, and to ensure that reported incidents are handled independently and impartially. We have a hotline in place to encourage employees and other stakeholders to report confirmed or suspected misconducts including direct or indirect fraud, bribery and corruption, as well as violations of corporate policies, rules and regulations and ethical guidelines. Staff members are also encouraged to raise concern on controversial behaviors through other communication channels as appropriate, such as their supervisors and the Human Resources Department.

The Compliance Department archives and screens all issues reported, conducts independent investigations for eligible cases and produces investigation reports. We respect confidentiality of whistleblowing, keep the reported matter and the identities of the whistleblower and the person being reported strictly confidential. We assess potential situations that may cause a conflict of interest in the process and make necessary avoidance arrangement. With regard to confirmed violation, the Group takes action based on relevant internal policies, and is obligated to hand over suspected criminal offence to law enforcement agencies as appropriate.

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# **Innovations for the Benefit of Patients**

Genor has been strategically focusing on the therapeutic areas particularly in oncology, immunological and other diseases areas that present substantial unmet medical needs; potential global FIC and BIC products, and molecular research with the greatest potential to produce clinically effective and commercially viable drugs. The Group has independently developed product pipeline with sufficient

capabilities to identify new molecular targets, accelerate cell line development (CLD), culture process scale-up, early clinical formulation development and clinical trial development programs. Concurrently, laying emphasis on the quality and pace of driving the clinical development pipeline, the Group also explores external licensing collaboration to boost its intellectual property rights reserve. 03

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- CMC Capabilities Allowing for Efficiency and Scalability
- Clinical Trials Progressing with Speed
- Sufficient Medicine Supply Prioritising Patient Needs
- Innovative Strength Expediting Intellectual Property Rights Accumulation



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# **Regulatory Reforms Nurturing Industry Growth**

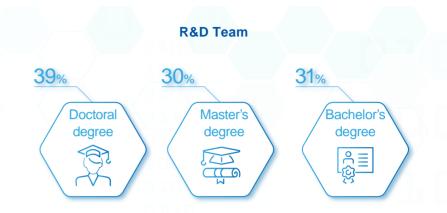
In recent years, the National Medical Products Administration (NMPA) has continued to enhance its drug evaluation standards and guidelines to the global level. The R&D of new drugs in China is experiencing rapid growth, and drugs with new targets and new mechanisms have accelerated into clinical development. The global pharmaceutical market has been witnessing the emergence of a range of independently-developed new drugs in China.

On 10 May 2022, the National Development and Reform Commission issued the "14th Five-Year Plan for the Development of Bioeconomy", China's first five-year plan for the biopharma sector with specific deliverables. The 20th National Congress of the Chinese Communist Party also listed biopharma in its report as one of the key domains for building an innovation-driven country. Domestic substitution of high-guality innovative drugs has become an important driver for the development of China's pharmaceutical industry.

# **Differentiated Innovation Serving Unmet Medical Needs**

# Seek Differentiation in New Drug Development

Genor has successfully built a platform for early discovery of FIC/differentiators, TCEs, bispecific/multispecific antibodies in immuneoncology and dual anti-ADC development. We focus on products with global FIC and BIC potential, as well as molecular studies that offer the greatest potential to drive further production of clinically effective and commercially viable drugs.



In 2022, our Chief Scientific Officer Dr. Han Shuhua and her team published three academic articles in the periodical of American Association for Cancer Research ("AACR").





Re: AACR Annual Meeting 2022



Dr. HAN Shuhua also delivered a

speech entitled "T-cell engager ("TCE") for BsAb/TsAb drug development" as a guest speaker at the "BIT - 5th 'Truesaw Antibody Drug Focus Summit".

Abstract Control Number: 7951 Title: Development of GB2101, a novel anit-CCR8 antibody for cancer treatment

Abstract Control Number: 7941

Title: Characterisation of GB263T, a tri-specific antibody against EGFR/cMET/cMET for NSCLC



Title: Development of GB2102, a novel and highly differentiated anti-FGFR2b antibody for the treatment of gastric cancer

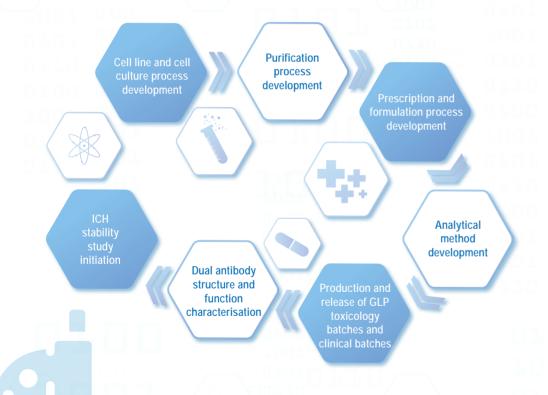
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During the Reporting Period, Genor's R&D team was in the process of conducting five global BIC bi-specific/multi-specific antibodies projects, and was driving 10 R&D projects involving different molecular forms.

CMC's main work from amino acid sequence after new drug discovery to clinical trial (CTA) application submission involves the following steps:



Taking **GB261 (CD20/CD3, bispecific antibody)** as an example, GB261 is the first T-cell engager with ultra-low affinity to bind CD3 and has Fc-enabled functions (ADCC and CDC). GB261 significantly inhibits rituximab-resistant cancer cell proliferation in both vitro assays and vivo models. With T-cell activation, GB261 induces less cytokine release compared with compounds in the same class. Thus, GB261 is a highly potent bispecific therapeutic antibody for B cell malignancies. It has the potential to be a better and safer T-cell engager with competitive advantages over other CD3/CD20 agents.

To date, Genor has put into operation several clinical centres for GB261 (CD20/CD3, BsAb) in Australia and China. Of which, the Group has already obtained preliminary clinical POC data in the FIH clinical trial of GB261 (CD20/CD3, BsAb) in Australia, which are consistent with the molecular design mechanism of GB261. This indicates a good safety, pharmacokinetic profile and clinical antitumor activities. Besides, the high-dose group is currently in dose escalation.

In order to diversify its R&D pipeline, Genor has explored collaborative opportunities with several international biotech companies and evaluated their strengths and competencies respectively, so as to seek joint R&D efforts. During the year, Genor entered into a cooperative development agreement with Suzhou Abogen Biosciences Co., Ltd to jointly develop globally innovative mRNA products. Genor's biological antibody development platform will be integrated with Abogen's mRNA technology platform to enable both companies to jointly research and develop mRNA drugs for tumor treatment.

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# **CMC Capabilities Allowing for Efficiency and Scalability**

Genor is well-equipped with internationally advanced process development capabilities in chemistry, manufacturing and quality control, as well as preclinical and clinical drug manufacturing capabilities. By collaborating with third-party contract research organisations (CROs) and complying with the standards of NMPA and FDA, the Group is committed to conducting clinical trials in Australia, China and the United States. At the same time, Genor continues to strengthen its own GMP and other relevant internal systems.

Genor adopts a results-oriented perspective when it comes to developing and strengthening its own CMC capabilities and operational practices, focusing on the safety and efficacy of drugs for patients, and building its own process development and quality assurance system through key technologies and modularised process development. The Group emphasises the integration of efficacy, efficiency and cost-effectiveness, and apply it across aspects such as development suitability, analytic methodology, yields, stability, transferability and scalability.

The IND-enabling works of CMC from the lead selection after drug discovery to clinical trial application (CTAs) submission includes:



Cell Line and cell culture development Purification Development Formulation Development Analytical Methods Development GLP Tox Lot and Clinical Lot manufacturing and release BsAb structural and functional characterisation

stability studies

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(3)

The CMC team of Genor has addressed and solved critical points of various processes, such as difficult and unstable expression of complex molecules of bi-specific/multi-specific antibodies, removal of homodimer impurities, and unstable intermediates, demonstrating our strength and strong execution.

CMC fully supports projects in all phases from new drug discovery, clinical use to commercial manufacturing:

- (1) R&D: facilitate R&D projects to IND development
- (2) Clinical application: Support the completion of IND projects GB261 (CD20/CD3) and GB263T (EGFR/cMET/cMET) related research and preparation of approval materials, so as to ensure the IND approval.
  - Late clinical stage: Promote the completion of the API process validation for the late clinical stage project GB491 (Lerociclib) and initiate the formulation process validation for this project.

The clinical study phase of the bi-specific antibody molecule GB261 and the tri-specific antibody molecule GB263T took 16 and 14 months respectively, from development of molecule after its acquisition to clinical trial application (CTA), which is ahead of the industry average of 15 to 18 months.



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# Clinical Trials Progressing with Speed

The Group has mapped out product pipelines in line with its overall development goals, of which a plan of clinical trials has been developed with the uncompromising principle of safeguarding patient safety. Our clinical programs adhere to sound medical ethics in light of the *Guide on Audit by Ethics Committee*. The Group scales clinical programs through a collaboration model with CRO, while performs its role to safeguard the integrity of trial data and facilitate progress in researches, so as to bring better treatment options for patients sooner.

The operational system of the Group's clinical research meets the requirements of the *Good Clinical Practice* (GCP) and ICH-GCP (The International Council for Harmonisation, ICH). Our team has years GCP experience has developed related internal policies, including the *Technical Guideline for Clinical Trial Data Management* and the *Code for Clinical Trial Quality Management*.

The clinical development team leverages the CRO's network on hospitals and investigators, its comprehensive service system and best-in-class quality standards to effectively propel clinical research programs in both China and Australia. At the same time, we enforce the oversight on CRO's operational compliance, data authenticity and reliability, thus ensuring the stability, safety and efficacy of the investigational drug. At Genor, each clinical trial is equipped with an electronic data capture (EDC) system that interfaces with the CRO and the investigators, where the investigator uses a coded ID assigned to each subject who remains anonymous to Genor, to manage trial-related information and data pertaining to the individual. These arrangements allows Genor access to subjects' trial data without revealing personal details. In addition, we regularly review our partners' practices to ensure they are compliant with the protection of subjects' personal information and privacy. As an integral part of clinical trials, the Group has purchased liability insurance for all subjects participating in clinical trials to ensure ample protection in case of serious adverse effects (SAEs).

Following the launch of the Australian clinical trials, the Group founded a project team in Australia to reinforce the local management and operation in 2022. The Group's well-established clinical development and trial system, which covers both China and Australia, encompasses clinical research quality management in clinical operations, medical monitoring, data management and SAEs.

The Genor Scientific Advisory Board (SAB), which is made up by several world-renowned experts in tumour immunology and clinical oncology, participated and offered a more global perspective on the innovative value of projects, evaluated and advised on Genor's FIC and BIC pipeline development. They will also help facilitate the clinical development of drug candidates in China, the United States, Australia and Europe.

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Despite the impacts of the pandemic and geopolitics, Genor completed the following clinical projects in 2022:

Product	Indication	Positioning	Stage
GB491 (Lerociclib)	HR+/HER2- BC (Breast Cancer)	Novel, potent, selective oral bioavailable CDK4/6 inhibitor	Patients have been enrolled for the second line and first line phase III clinical trials.
			Several clinical centres have been opened in Australia and China.
GB261 (CD20/CD3, BsAb)	NHL (Non Hodgkins Lymphoma)	Potential Best in Class CD20/CD3 bi-specific antibodies	The preliminary clinical Proof of Concept (POC) data was obtained in the first-in-human (FIH) clinical trial in Australia
			The first patient was dosed in the phase I/II clinical trials in China.
GB263T (EGFR/	NSCLC (non-small cell	The first tri- specific antibody of EGFR/cMET/ cMET in the world	The first patient was dosed in the first-in-human (FIH) clinical trial in Australia
cMET, TsAb)	cMET/ ET, TsAb)		The first patient was dosed in the phase I/II clinical trials in China.
			Finished monotherapy clinical trials.
			Completed a dose escalation up to 400ug.
GB492 (IMSA101)	Solid Tumors	Potential Best in Class STING agonist	The clinical trial of the new drug combining GB492 (IMSA101) with Aibining® (GB226, Geptanolimab) was approved by the Human Genetic Resources Administration Office of the PRC.

# Sufficient Medicine Supply Prioritising Patient Needs

Genor prioritises patient interests when designing medication plans for clinical trials. In 2022, despite mounting challenges in operation, manufacturing, and continuous provision of reagents in particular, there wasn't a moment that the management and staff members were in disarray about the mission of the business they are in and their responsibilities to ensure continuous treatment of patients. To that end, the Group developed an emergency response system, including appeals to authorities concerned on its life-critical duties. The Group marshalled resources to ensure timely arrival and turnover of imported materials, as well as push forward R&D and clinical trial projects. The concerted efforts of Genor's team led to the uninterrupted supply of drugs for clinical projects during the pandemic, and the early completion of enrolment of patients in Phase III clinical project GB491 (Lerociclib) two months ahead of schedule.

During the pandemic, Genor overcame multiple difficulties to ensure that the clinical trial subjects have continued access to clinical trial/combination therapy drugs, avoid treatment interruptions, and achieve optimal outcomes.

- A) Develop the capability to build qualified pharmaceutical warehouses efficiently to deploy drugs for clinical programs in multiple regions, and provide medications to patients through local distributors to prevent the risk of drug discontinuity.
- B) Look for specialised shipping channels and vehicles for drug delivery.
- C) Help patients find local resources, such as municipal helplines, so that patients can seek out nearby hospitals for post-medication efficacy and safety checks during the pandemic.



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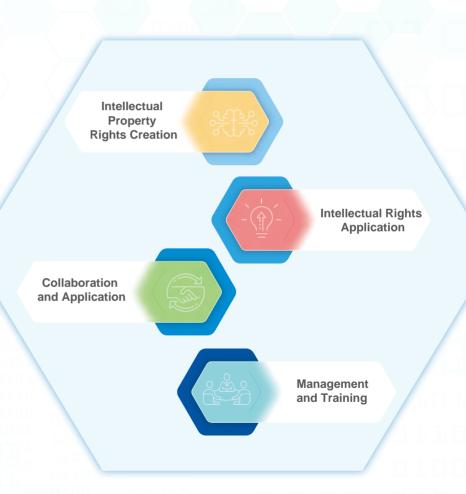
# Innovative Strength Expediting Intellectual Property Rights Accumulation

Genor attaches great importance to commercial information security and intellectual property rights protection. In addition to abiding by the *Patent Law of the People's Republic of China*, the *Trademark Law of the People's Republic of China*, the Copyright Law of the People's Republic of China and other relevant laws and regulations, the Group has established management policies internally, including the *Confidentiality and IP Management System*, the *Management Measures of Invention Submission and Patent Evaluation*, the *Management Code* and the *Trademark Use Code*.

The Group has set up different classification of confidentiality, scope of use and authorisation procedures for different types of confidential business information. For information that needs to be disclosed, we complete a review process according to internal policies, and where a third party is involved in the process, a confidentiality agreement is signed.

The Group's Regulatory Affairs and Intellectual Property Rights Departments are responsible for the management of intellectual property rights, invention evaluation, publication of papers, trademark registration and protection. They are also in charge of developing the registration strategy of independent intellectual property rights while taking into account the industry trends and Genor's R&D progress.

Our strength and achievements in new drug R&D led to a decent amount of intellectual property rights. As of the end of 2022, the Group applied for more than 90 patents for inventions and PCT patent applications, including 6 applications made during the year; the cumulative number of granted patents was 32, including 4 granted patents during the year. The Group was awarded the "Top 100 Chinese Pharmaceutical Innovation Companies 2022" by the Yaozh.com, the Expert Committee of Pharmaceutical R&D Ranking and the Organising Committee of 2022 China Pharmaceutical R&D Innovation Summit.





# Quality System Driven by Efficacy and Safety

Genor is committed to providing effective and safe drugs for clinical and commercial supply to physicians and patients, with a system that ensures conformity with the intended use and registration requirements throughout the process from clinical development, CMC to commercial manufacturing, product release, storage and delivery. The Group assumes responsibility together with its partners, such as CRO, suppliers, CSO and distributors, in the efficacy and safety of drugs produced.

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- Quality Assurance System
- Resilient value chain with suppliers

#### **Genor Quality Pledge**

"Supported by a quality management system that is upgraded on an on-going basis, Genor is committed to providing safe, effective and high-quality drugs that meet the needs of the patients and the regulators."



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# **Quality Assurance System**

## **Compliance with Relevant Laws and Regulations**

As the Group operates in a highly regulated industry, it takes compliance at the heart of its business, ensuring strict compliance with applicable national laws and regulations, such as the Drug Administration Law (DAL), the Measures for the Administration of Drug Registration, the Good Manufacturing Practices (GMP), the Measures for the Supervision and Administration of Drug Production, and the Measures for the Reporting and Monitoring of Adverse Drug Reactions.

Genor Biopharma has established a quality system that complements its different stages of product development and management priorities, such that it is not only compliant with the legal requirements above but also the ICH Q10 guidelines and other guality requirements. The Group seeks to continuously enhance its guality management over the entire product lifecycle across new drug development, clinical trials, technology transfer and commercial manufacturing.

During the year, there were new releases and revisions issued by the regulator, such as the Measures for the Administration of for Drug Recalls, the Regulation on the Administration of Annual Reports on Drugs, the Guiding Principles for Pharmacovigilance Inspections, the Identification Specification for Drug Traceability Code and the Display Specification for Consumer Enguiry Results of Drug Traceability under the DAL, as well as the appendix of Investigational Products (For Trial Implementation) to the GMP. The Group updated its internal policies and processes as and when appropriate to ensure operational compliance.

## **Effective Systems and Policies**

Our established quality system comprises standard management process (SMP) and operating procedures (SOP) followed and monitored in operations, whereby corrective and preventive measures are generated with effective assessment and training requirements. With regard to external collaboration, the Group also strives to have a thorough understanding about quality assurance in its partnership due diligence before proceeding with quality agreement, which will be followed and controlled in operations.

Genor Biopharma has formed collaboration in clinical trials with CROs, for instance Hangzhou Tigermed Consulting Co. Ltd., whose global network in research hospitals and investigators, together with its proven quality system including standards and operating procedures, are effectively leveraged to help drive its projects. At the same time, we operate an established quality system covering clinical practices in clinical operation, medical investigation, data management and pharmacovigilance.

**Documentation Structure of Quality Management System** 



Genor's GMP system comes with four levels in documentation structure, with its Quality Manual setting the ultimate framework and principles, as well as standards and requirements for each practice. The second level of Standard Management Procedures covers guality control documents in manufacturing quality practices, technology transfer management process, deviation investigation and handling process, and product release process. The third and fourth levels are STP/SOP and record management, respectively.

The Group's guality management system has an effective corrective and preventive process underpinned by its operating rules for the Management of Corrective and Preventive Measures to ensure continued improvement in deviations, complaints, recalls, internal and external inspections and processes in accordance with quality monitoring trends as appropriate. During the Reporting Period, the Group did not record any customer complaints about products and services.



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THE GROUP'S QUALITY MANAGEMENT SYSTEM



Genor's quality management system encompasses the BsAb/TsAb laboratory located in Los Angeles, the United States, R&D and clinical research laboratory located in Zhangjiang of Shanghai, China, clinical investigation centre in Australia, and GMP manufacturing facility in Yuxi of Yunnan, China. During the Reporting Period, the Group successfully transferred its clinical medication manufacturing from Zhangjiang to Yuxi to concentrate its manufacturing capability. As at the end of 2022, batches of GB261 of clinical trial uses were manufactured and delivered from Yuxi facility.

The labels of Genor's investigational medicine and registered drug are regulated by Provisions on the *Administration of Pharmaceutical Directions and Labels* and approved by NMPA. Genor has established labelling quality management processes, for instance, checking the accuracy of product name, batch number and validity period before packaging. The label of investigational medicinal products is required to meet the relevant requirements of GCP, and indicates the words "only for clinical trial" or similar instructions. According to the *Advertising Law of the People's Republic of China*, advertising for prescription drugs is prohibited. The Group's clinical drugs and approved drugs are prescription drugs and therefore are not involved in such activities.

## **Clear Roles and Responsibilities**

Genor's CEO and its senior management are responsible for driving the implementation of the Group's quality management system. The quality assurance management team takes specific actions in quality system optimisation and supervises the conformity of quality management tasks including the establishment, implementation and maintenance of all necessary operational processes. Our quality management system has adopted internal and external audits, a necessary step taken to ensure its compliance.

Our Drug Safety Committee observes its *Drug Safety Committee Charter* and is responsible for the deliberation of major risks, material or emergent drug incidents and related handling, decisions on risk control and management, as well as pharmacovigilance-related material decisions. Adhering to the ICH Q9 guidelines, we evaluate, control, communicate and review quality risks with a retrospective or prospective approach in light of the product's lifecycle. Moreover, we utilise tools like the FMEA and HACCP frameworks to gauge risk impact on critical controls, systems and key processes, and develop mitigation plans correspondingly.

Genor is committed to pharmacovigilance which is a shared responsibility with our investigators, sponsor hospitals and CROs. In line with industry regulations, norms and requirements, such as the *Specifications for Pharmacovigilance Quality Management*, the *Guiding Principles for Pharmacovigilance Inspections*, and the *Measures for the Reporting and Monitoring of Adverse Drug Reactions*, we have set policies of *Complaint Management on Drugs* and *Drug Recall Management* in addition to multiple adverse reaction reporting and communication channels, ensuring that all these are operated following defined approach and responsiveness. During the Reporting Period, we updated the key documents for our pharmacovigilance practice, including the development of guidelines and formulation of a pharmacovigilance agreement for contract manufacturers relating to launched products.





We continuously improve quality control management by upgrading quality control organisational structure and documentation system, with a total of 225 sampling and testing management process documentation and records, and completed method confirmation of 32 in-house testings on accessory and packaging materials following termination of previously outsourced services.

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**Management Process on Adverse Events Report** 

Report and monitor of adverse drug events strictly following various guidelines from international institutions and the national regulations in China. Set up company account, uploaded registered products' Compliance information and online delivery channel in the local ADR centres where we operate during the year, participated in phamacovigilance core competence study program sponsored by the Centre for Drug Evaluation, NMPA. Establish procedures for individual cases of adverse events on clinical and therapeutic drugs, as well as SOP covering report Process collection, processing, quality and training. For clinical drugs, inform patients on drug safety-related information and potential risks by providing Informed Consent Transparency Form. For therapeutic drugs, outline adverse events-related information for users. Set up and made public multiple reporting channels, including telephone hotline, Genor's corporate website and corporate WeChat account. etc. Channels Provide training to employees, CSO, distributors and hospitals reinforcing reporting requirements. Imminently upload reported cases to the drug safety database, and categorise reports based on the degree of severity, relevancy Recordand likelihood in accordance with regulatory agency reporting keeping timelines. Codify reported cases in sequence, stay sceptical on incomplete Handling information, and deliver conclusion to reporting parties. Conduct relevance assessment with evidence and rationale. Medical exercise judgement on probability/predictability. Evaluation Submit reported cases to the regulator via electronic channel Report Submission within required time frame to ensure compliance.

# **Quality Controls Progress Steadily**

Driven by a change of company strategy in 2022, the Group's priority of quality management and assurance was centred around two aspects, namely the quality management system for R&D to facilitate the CRO model adopted and the quality management system surrounding our qualification under the Marketing Authorization Holder (MAH) system in China. During the year, our quality management team conducted three special meetings for quality reviews, particularly on the systemic effectiveness of the Group's quality management through impact analysis on the causes of deviation and change occurred. Resulting improvement actions were proposed as part of the continuous improvement initiative.

# **Training Grooms Quality Culture**

The strict implementation of quality system and steady improvement on quality standards are achieved with the contribution from each and every employee who has been sustaining a good level of quality awareness and quality performance. Our regular quality training for employees, as an important component of our quality system, is formalised under the *Operating Rules for the Administration of Employee Quality Trainings*, and delivered in many forms during the year.

Our Quality Assurance Department discusses with each business and functional department when determining annual quality training plan, including induction courses for new joiners, recurring trainings for existing employees and new posting trainings across a breadth of subjects, such as GMP, post operation and production safety. The results effectiveness assessment will cover both training content and participants' appraisal, aiming to uplift the capabilities of employees and constantly improve the training programs. 1,344 person counts participated in the trainings during the Reporting Period. All participants passed the assessment.

In addition to the annual training, the Group also organised study programs on new or revised regulations issued in 2022, whereby internal policies and processes were adjusted accordingly to strengthen compliance awareness and practices.



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# **Resilient Value Chain with Suppliers**

It has become a norm in the highly regulated biotech industry that companies engage various contracted services due to division of skills and specialisations. Genor has deployed its external partnership strategy balancing the costs and time required between self-built and externally commissioned to optimise cost effectiveness. As a result, the Group has formed a series of major collaborations with qualified professional companies that provide complementary capabilities in early-stage R&D, clinical trials and marketing and sales.

## **Policy and Management**

Genor has three types of suppliers namely service providers, materials suppliers and equipment producers. Under the overarching principle in the *Management Procedures for Procurement*, corresponding management approaches are developed, including the *Audit Procedures for Materials Suppliers*, the *Procurement Management Rules for Non-GMP Materials Suppliers*, the *Management Procedures for General Suppliers* and the *Policy on the Management of Clinical Investigators*. During our supplier selection and annual review process, we require suppliers to provide environmental and other qualification to ensure they meet relevant requirements.

Genor emphasises quality and delivery capability in its procurement activity, assessing the potential to deliver value-added and after-sales service, as well as reviewing relevant track records. Our service providers include CRO, CSO, logistic providers, testing and validation services, and audit agency. All collaborations are grounded on a satisfactory outcome from our evaluation on quality standards, compliance performance, data and system reliability, medical ethics, as well as risk assessment. We further implement *the Special Provisions on Anti-bribery and Anti-corruption* — a policy issued in 2021, for a formal pledge from our suppliers.

Genor operates a set of processes and procedures for supplier management from screening, due diligence, entry, to quality tracking, annual review and audit, delivered by a cross-functional taskforce including procurement, quality assurance, legal affairs, contract management and internal audit. The assessment covers various areas but mainly on scarcity, traceability, quality, delivery capability, pricing and responsiveness. A supplier annual audit plan, with a combination of both onsite and external third-party audits, is developed to proactively monitor and mitigate risks.

All material and equipment suppliers are GMP and/or ISO certified, and additional certifications on safety and sources are required as and when products supplied contain animal-related raw materials. Three categories of material suppliers are defined according to product quality and impact on patients' safety, and quality assurance agreements are required for suppliers of the first and second categories.

With our industry-leading technical capabilities and an enduring quality management system, the Group has been gradually introducing local suppliers while securing the same level of quality, so as to mitigate supply disruption risks caused by geopolitical tensions and climate change, as well as reduce costs and further increase our drug accessibility. It is expected that supplier localisation would help foster industry capabilities in R&D and quality management in China.

#### **Procurement Practice**

In 2022, Genor further optimised its procurement system, setting up a supply chain management department that takes charge of procurement, logistics and sales management, following its consolidation of production capacity to Yuxi. This new department is also responsible for the strategy and operation of supply chain management including resource allocation, aiming to improve efficiency and reduce risk. It is critical to ensure quality at the stage of procurement, whereby materials, in particular those require stable external environment, are tested with relevant information verified and duly recorded before moving to our environment-controlled storage as appropriate. During the year, the procurement team successfully fulfilled its responsibilities, despite the organisational change and delivery challenges induced by the COVID-19 pandemic control measures.

The procurement team completed its declaration on conflict of interests in 2022, and conducted review according to *Employee Code of Conduct and Business Ethics*. We also amended supplier entry evaluation process to reflect that priority will be given to suppliers who are ISO 14001 certified.

During the Reporting Period, the Group had 2,651 suppliers globally registered in its system:

Shanghai,	Other locations,	Hong Kong, Macau	The United
China	China	and Taiwan, China	States
785	1,816	5	



# 05



# Partnership Model to Achieve Comprehensive Coverage

In view of the capital market's valuation correction for the biopharma sector and the uncertainties brought by the pandemic, Genor adopted a model of collaborating with CSO to improve operational efficiency with optimal organisational agility, complementing its stage of development and leveraging the rigor and availability of professional division in the pharmaceutical industry during the Reporting Period. The established scale and specialty of the CSO in medical science promotion allow Genor to reach extensive coverage the targeted hospital network efficiently, whereby the physicians will have access to and build knowledge about the indications and differentiated efficacy of Genor's approved drug products, and ultimately serve the patients in need which is the last mile of accessibility.

- Emphasise Strength to Select Qualified Partners
- Organise Trainings to Ensure Knowledge Sharing
- Collaborate for Quality Delivery



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# **Emphasise Strength to Select Qualified Partners**

While focusing on a highly differentiated drug pipeline, Genor seeks to work with partners with shared principles on corporate culture and have sound business ethics. The Group evaluates prospective partners primarily from four areas, including strategic fit, compliance, ethics and culture, and professionalism in academic promotion.

Look for CSO with relevant track record and expertise for the indications of our medical products have been or about to be approved to achieve sound compatibility with marketing strategy.

Conduct due diligence to assess GSP qualification, verify past compliance performance, and identify gaps in its operation system, as well as review relevant principles of medical ethics.

Ethics and Culture

Strategic

Compliance

Conduct due diligence to evaluate corporate culture and business ethics performance, especially on principles and management systems with respect to conflict of interests, and anti-corruption.

Academic Promotion

Examine the team's academic capabilities, market research capabilities, previous medical science promotion achievements, and self-owned promotional channels and resources in specific regions and target markets, including network of hospitals and physicians.

In addition to the commercial and technical terms reached, the Group and the partnering CSO also agree on ways to manage practices such as conflict-of-interest, anti-corruption and anti-commercial bribery, among them an *Anti-Commercial Bribery Commitment* must be signed.



# Organise Trainings to Ensure Knowledge Sharing

The selected CSO partner plays an important role in representing Genor engaging with hospitals during medical science promotion and health education. Therefore, their understanding of Genor and its drug products will directly affect the effective implementation of promotion strategies and Genor's corporate reputation. In view of this, we strive to provide ample support for CSO throughout the collaboration, including developing product positioning strategy, medical information, marketing materials, sharing professional knowledge, and performing inspection, supervision and assessment.

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The medical, marketing and other departments of Genor organise a series of training courses on the proposed medical products, including drug effects, efficacy and adverse events. The main trainings are as follows:

Introduce indications, efficacy and characteristics. Ensure that CSO build a good level of knowledge of the product and **Pharmaceutical** communicate as appropriate with the hospitals (including relevant pharmacy committees, pharmacy departments, department heads and physicians).

Pharmacology and **Medical Information** 

Expertise

Deepen CSO's knowledge about rational-drug-use, disease prevention and control theory, and knowledge on pharmacology and science-based approach and methodoloav.

**Pharmaceutical** Market Knowledge Share latest policy trends, and their impact on Genor and its product to be promoted.

Pharmacovigilance and Adverse Events

**Anti-Corruption** 

Introduce Genor's existing pharmacovigilance system, process and response timeframe requirement, the adverse events, drug-drug interactions and medication errors of the drugs to be marketed. Ensure that the CSO reports adverse events according to the protocol.

Introduce Genor's anti-corruption and accountability system, and compliance culture.

Genor abides by the applicable laws and regulations, including the Announcement on Matters Concerning Direct Reporting of Adverse Reactions by Drug Marketing Authorisation Holders, the Notice on Issuance of Guidelines for Collection and Reporting of Individual Adverse Drug Reactions, the Adverse Drug Reaction Event Reporting Form for Listing License Holders and Instructions for Completing the Form, and the E2B Implementation Guide for Post-Marketing Individual Safety Reporting (CDR). The Group has worked with CSO, distributors and hospitals establishing adverse event reporting and communication channels, in addition to a network of third-party call centres across the country for reporting from the public. Regarding the monitoring, reporting and handling of adverse events, the Group organised dedicated training sessions for our staff and call centre personnels during the year to ensure the timeliness and quality of adverse event reporting.

# **Collaborate for Quality Delivery**

In February 2022, Genor obtained approval from the NMPA for the launch of Jiayoujian 佳佑健® (GB242, Infliximab), an autoimmune therapeutic drug. During the Reporting Period, the Group obtained enlisting approvals for online procurement in 17 provinces, and continuously worked to obtain medical insurance reimbursement codes with relevant filing, so that Jiayoujian 佳佑健® can be widely used to treat patients.

Our partnering CSO organised various activities, including medical forums, academic seminars, and patient-physician sharing sessions, to introduce the indications and efficacy to physicians and professionals in the target markets. At the same time, Genor has partnered with eight distributors who are qualified in pharmaceutical cold chain transportation and have respective regional capabilities in China. The distributors are required to comply with standard operating procedures in delivering assigned product, with undertaking to a Quality Assurance Agreement, that covers conformity on drug storage and transport conditions from factory to hospital or pharmacies, within defined time frame among other requirements.





# Employment, and Employee Care and Development

The COVID-19 pandemic and complex geopolitics gave rise to unprecedented risks and challenges to many sectors, including biopharmaceuticals. In light of this, Genor optimise its business structure by reducing overlapping responsibilities and facilities to sustain an agile organisation after much deliberation on its priorities and strengths. We believe that this change would facilitate the Group to concentrate on its core businesses and deliver focused growth when forging ahead.

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- Optimise the structure for Agility and Vitality
- Employment Practices
- Communication and Care
- Staff Training and Development
- Production Safety and Occupational Health
- Community Building



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# **Optimise the Structure for Agility** and Vitality

# **Organisational Transformation**

It is imperative that we communicate the transformational changes within the organisation with our employees in an open and honest manner. A dedicated working group was set up and a work schedule was mapped out in the spirit of optimal transparency. In addition to strictly following all applicable laws and regulations for the severance process, we offered assistance for a calm transition as smooth as it can possibly be. For instance, we introduced industry vacancies, organised onsite recruitment presentations, conducted small-scale interview counselling and recommended headhunters as appropriate. In the end, we held a gathering for the leavers from the Commercial Operations, expressing gratitude to the team's past contributions.

Dr. Guo Feng, Chairman and CEO of the Group, together with his senior management team, conducted a number of candid conversations with the remaining staff members, sharing the rationale behind these changes, the resulting growth opportunities ahead and what held for personal career development. Such visible leadership and engagement helped motivate employees and realign goals for the Group's future.



# **Employment Practices**

# **Corporate Culture and Hiring Principles**

As a biotechnology company, Genor upholds a culture of openness and transparency, cultivates the spirit of mutual trust, respect and courage, advocates for equity, fairness and fact-based approach. The Group is dedicated to building a good employment relationship featuring a sense of belonging and mutual support for a shared development with the employees who are effectively powerful drivers in achieving the Group's vision and goals.

The Group strictly complies with relevant laws and regulations, including the Labor Law of the People's Republic of China, the Labor Contract Law of the People's Republic of China, the Law of the People's Republic of China on the Protection of Minors, the Social Insurance Law of the People's Republic of China, the Provisions on the Prohibition of Using Child Labor and the Law of the People's Republic of China on the Protection of Women's Rights and Interests. By referencing the aforesaid laws and regulations, the Group has in place internal policies such as the Regulations on Employment, Labour Contracts, and Probation Periods to standardise its employment practices.

Our hiring practices follow the principles of openness, fairness and impartiality, and takes a merit-based and free will approach regardless of ethnicity, race, age, gender, religion and political position. We adhere to gender equity, with equal pay for the same role and responsibilities. We strictly prohibit any form of forced labour or child labour, and require all new joiners to provide valid identification documents for verification. Any violations, if found, will be handled without delay according to the regulations concerned.



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The Group provides employees with competitive compensation and welfare packages. Our remuneration primarily encompasses basic salary, various bonuses and allowances, with a portion of variables depending on performance. Mid- and senior-level employees and certain key frontline employees have also participated in the employee stock option plan. We conduct annual performance appraisals for all employees, and related results will be used as critical inputs for annual performance bonuses, salary increments, promotions and career development. All employees of Genor are eligible for leaves such as paid holidays, statutory holidays, annual leave, marriage leave, compassionate leave, maternity leave and paternity leave.

Following the addition of childcare leave in 2021 in accordance with the *Decision of the Standing Committee of the National People's Congress to Amend the Population and Family Planning Law of the People's Republic of China*, we have been in the course of making adaptive updates of the relevant content in our employee handbook upon the new revisions made to the *Law of the People's Republic of China on the Protection of Women's Rights and Interests* in October 2022.

We also make full and timely payments of the pension, medical insurance, unemployment insurance, work-related injury insurance, maternity insurance and housing provident fund for employees in accordance with national and local laws and regulations. Moreover, various extra benefits are provided, such as annual health check-ups and supplementary commercial healthcare insurance.

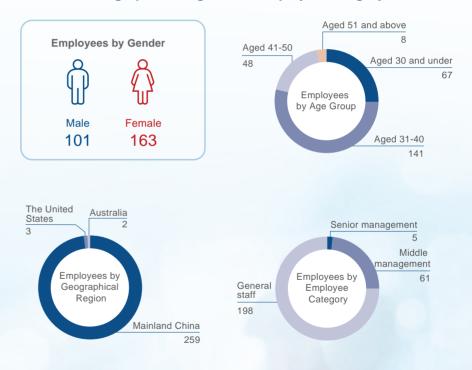
#### Trade Union Work at Manufacturing Site in Yuxi, Yunnan

Observing the *Trade Union Law of the People's Republic of China*, a local trade union has been up and running in Genor's manufacturing site in Yuxi, where all employees have entered into collective contract agreement following collective wage negotiation, thus protecting employees' rights and interests in the areas of remuneration, working hours, leave and holidays, work safety and health, insurances and other welfare.

In 2022, the trade union completed its 18th employee medical mutual aid programme, and organised employees to participate in the Ankang Cup activity arranged by a regional trade union covering production safety education, training and drills. A dual-cancer screening programme specifically for female employees also took place during the year.

As at 31 December 2022, Genor had a total of 264 full-time employees, 400 people fewer on a year-on-year basis. There were also 2 part-time employees. Overall employee turnover rate was 93.51%. The Group had a total of 85 R&D staff members in 3 countries, and those holding master's and doctoral degrees constituted 35.23% of the total number of employees.

#### Information on Employee Distribution by Gender, Age Group, Geographical Region and Employee Category





Environmental, Social and Governance Strategy Innovations for the Benefit of Patients Quality System

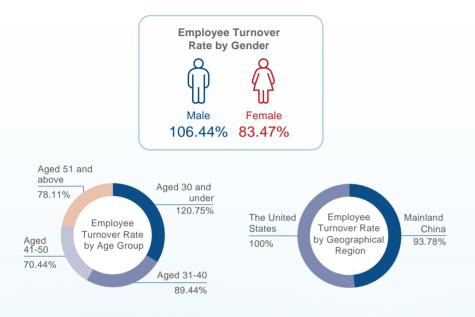
and Safety

Driven by Efficacy

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Employment, and Employee Care and Development Operations and Manufacturing Unveil Environmental Benefits

In 2022, the Group's employee turnover rates by category were as follows:



# **Communication and Care**

We maintain a harmonious employee relationship underpinned by effective communication. We encourage our employees to express their honest views and have in place a number of communication platforms, such as CEO letters, townhall meetings and seminars, for transparent and timely interaction with employees keeping them abreast of the Group's major development. We also welcome their feedback on suggestions or questions through emails, telephone calls and face-to-face meetings to safeguard their access to higher management and cross-departmental teams.

Every time a project has reached its milestones, the Group brings together colleagues of all the departments involved in the project to celebrate the shared accomplishments and boost teams' morale. For instance, in March 2022, upon the official approval of Jiayoujian 佳佑健<sup>®</sup> (GB242, Infliximab), the project teams in Shanghai, Beijing and Yuxi gathered through a plenary meeting to share their delights as well as tough moments along every step of the journey from research and development to successful registration.

Faced with the disruption of business operation and absence of normal transport services brought about by the COVID-19 pandemic across China in 2022, Genor formulated its response strategy with much prudence, striving to protect the safety of employees and their families on the one hand and laid down its *COVID-19 Prevention and Control and Closed-loop Management Plan* on the other to perform continuous medicine supply. In addition, the Group marshalled resources for a full resumption of operation. At the times when the pandemic situations took a turn for the worse, Genor's manufacturing site in Yuxi twice invited Yixu Hospital of Traditional Chinese Medicine to send medical staff over to the campus to conduct nucleic acid tests for employees, so as to avoid the risk of getting cross infections that might be caused by frequent individual travels for testing.

During the pandemic in 2022, employees who could not be present at the workplace due to pandemic controls were offered the plan of working from home as appropriate. We also organised two rounds of delivery of daily necessities to employees who were in need of such supplies. In addition, subsidies were provided to those who returned to work in advance on the back of closed-loop production arrangements in Shanghai.

Genor employees return to work at Shanghai office







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# Staff Training and Development

Genor places great value on the development of employees and the training and motivation of talents. The Group has in place comprehensive training programmes and takes into consideration employees' individual career plans, so that they achieve personal career goals through delivering their work.



At the company level, the Group provides trainings for all new joiners, offering courses on compliance, legal affairs, safety management and human resources management through induction programmes. The Group also works with a third party professional online learning platform to provide a complete online training system for all employees. There are currently 35 groups of colleagues having their team learning accounts on the said platform.

Moreover, the Group conducts special trainings for different teams and positions to continuously improve their professional skills and work quality. Training courses held during the year covered professional trainings such as national pharmaceutical policy update, new policy consultation, pharmacovigilance and adverse events reporting, as well as skills-based trainings like safety management, hazardous chemicals management, pressure vessel operation, drug manufacturing site management and quality management. Furthermore, the Group provided cross-departmental and cross-post trainings for employees from the R&D and functional departments, and invited top experts in the industry to give lectures on the MAH system in pharmaceuticals.



The biopharmaceutical industry is advancing at a rapid pace, and the professional knowledge required for key positions are becoming increasingly demanding. With the continuous development and progression of the sector and its policies in China, certain professional positions such as pharmacovigilance, legal affairs,

compliance, human resources are also required to have standardised training and knowledge upgrade on an annual basis. Genor fully supports employees in relevant positions to duly participate in continuing professional development programmes available in the industry. During the Reporting Period, Genor recorded a total of 4,419 training hours, with an average training hours per employee stood at 10.33 hours. As the Group moved to optimise its business and organisational structure, no systematic recording was made on the training hour particulars during the year.





# **Production Safety and Occupational Health**

Genor never takes the occupational health and production safety related to its laboratories and manufacturing site lightly. Its environment, health and safety (EHS) management has established standards with cascaded management procedures at different levels for the betterment of the overall health of employees.

# **Production Safety**

Genor has all along taken occupational health and safety as the priority, and adheres to strict compliance with relevant laws and regulations, including the *Work Safety Law of the People's Republic of China*. At the same time, the Group has formulated internal policies such as the *EHS Manual*, the *Operating Procedures for Laboratory Safety Management*, the *Operational Procedures for Onsite Safety Inspections*, the *Operating Procedures for Confined Space Operation Management*, the *Operating Procedures for Occupational Health Management*, the *Operating Procedures for Safety Incidents/Accidents* and the *Emergency Response Plan for Production Safety Accidents*, etc.

Our manufacturing site implements the production safety management system consistently, and strictly follows 13 core principles including the production safety goals and responsibilities, compliance management, education and training, and operation safety.



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In terms of the storage and management of hazardous chemicals, we have established a series of policies, such as the Operating Procedures for the Management of Hazardous Chemicals, the Operating Procedures for the Management of Highly Toxic Chemicals, and the Operating Procedures for the Management of Precursor Chemicals. A special storage area has been made available with a dual-person dual-lock management protocol. To further identify, prevent and manage potential safety hazards at work sites, we have developed rules and policies including the Procedures for the Management of Hazard Source Identification, Evaluation and Control, the Procedures for Equipment Repair and Preventive Maintenance Management, the Operating Procedures for Fire Facilities/Equipment Management, the Operating Procedures for Special Equipment Management, and the Procedures for Special Gas and Gas Cylinder Management, etc.

The Group's manufacturing site in Yuxi has established a dual prevention mechanism, which evaluates and categorises safety risks, and conducts inspection and analysis of hidden hazards:

Ĵ	Hierarchical Safety Risk Control System
	entation: Implement differentiated and dynamic management and control in accordance with the principles of "Independent Investigation, Scientific Evaluation, Categorisation and Rating, and Hierarchical Control"

#### Tasks:

- Strengthen safety management to eliminate or minimise hazards
- Enhance accident prevention and control capabilities
- Effectively curb major production safety accidents and reduce safety risks

#### and Identification System

**Potential Hazard Screening** 

#### Tasks:

- Avoid breach of production safety laws, regulations, rules, standards, procedures and production safety management systems through hidden danger investigations
- Check other factors in production and operation activities so as to keep away from unsafe conditions of items that may lead to accidents; from unsafe behaviours of people; and from management deficiencies

During the year, Yuxi manufacturing site once again initiated its self-inspection programme of "Production Safety Hi-tech Recce", carrying out regular hidden danger inspection on internal safety risk points, convened special safety meetings, and launched month-long production safety activities revolving around the theme of "Complying with Work Safety Law, Being the Utmost Person of Responsibility" to maintain safety awareness among personnel at all levels. The Group organised a number of emergency drills, covering firefighting, special equipment accidents, chemical leakage, confined space operations, anti-terrorism and riot control, in order to improve the emergency handling capabilities of employees when confronting such incidents.





Additionally, for the sake of allowing for timely discovery and rectification of potential environmental hazards in the manufacturing process, the Group also kicked off drills based on its *Response Plan for Environmental Emergencies*, making sure that on-the-job personnel did master specific actions and measures to deal with emergencies such as equipment failures.

During the Reporting Period, the Group had no major production safety and fatal accidents, and the number of days lost due to workrelated injuries was zero.

Health and Safety Indicators	Unit	2022	2021	2020
Number of Work-related Fatalities	Person	0	0	0
Rate of Work-related Fatalities	%	0	0	0



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# **Occupational Health**

Strictly abiding by the Law of the People's Republic of China on the Prevention and Control of Occupational Diseases, the Provisions on the Supervision and Administration of Occupational Health at Work Sites and other relevant laws and regulations, Genor has formulated management policies in this respect, including the Policy on the Management of Occupational Hazard Monitoring and Evaluation, the Policy on Occupational Hazard Warning and Notification, the Policy on Emergency Response, Rescue and Management of Occupational Hazardous Accidents, the Policy on Emergency Handling and Reporting of Occupational Hazardous Accidents, the Policy on the Declaration of Occupational Hazard Items and the Policy on the Management of Personal Protective Equipment for Occupational Hazards, etc.

#### **Risk Identification**

The Group holds a firm grip on the supervision and administration of occupational health, and conducts thorough screening on occupational hazard factors in production sectors and laboratories. Having in place the *Occupational Hazard Pre-evaluation Report* and the *Special Chapter on Occupational Health*, the Group is devoted to detecting and evaluating occupational hazards on its production process and laboratories, and will entrust a professional third party to evaluate the effect of occupational hazard control in production areas, laboratories, air-conditioning control rooms, etc. every year with a move to strengthen its occupational health supervision.

#### **Risk Management and Prevention**

We will provide occupational disease verification, assessment and protection according to the nature of the job, and will conduct pre-job, annual and pre-exit occupational health check-ups for personnel in relevant positions. Occupational health monitoring records will be filed in a timely manner and occupational protection measures and equipment such as face masks, protective clothing and protective gloves will be adopted and provided as required by such positions. On top of these, we also inform related personnel of the occupational health information before the job, on site and during training to ensure informed employment and operational compliance:

#### **Pre-job Notification**

When new employees take up a job, and when employees change their job positions or job content during the labour contract period, we will inform them of the occupational hazard factors, possible occupational hazards and occupational hazard protection measures that exist in the said posts.

#### Onsite Notification of Job Operations

In the jobs where occupational hazards occur, warning signs are set up to remind personnel of the hazards and related protection measures taken.

#### Training Notification

Provide occupational health-related knowledge training to employees, bulk compile training materials, training records and other information into a portfolio, and have it filed for record.

The Group places its stress on occupational health and safety and keeps its communication channels open at all times. It encourages each employee to report occupational safety-related issues or demands through various channels, such as telephone calls, face-to-face discussion, WeChat, to department heads and trade unions.

# **Community Building**

It happened at the time that the Group was undergoing its organisational transformation during the year. Coupled with the impacts brought forth by the recurring waves of the COVID-19 pandemic, we had to temporarily suspend our participation in volunteer services for local communities and charities. Nevertheless, we look forward to continuing to fulfil our corporate social responsibilities in the foreseeable future.



# **Operations Unveil Environmental Benefits**

# **Climate Change Risk**

In December 2015, nearly two hundred countries signed the Paris Agreement at the UN Climate Change Conference (COP 21), aiming to significantly reduce GHG emissions from human activities and limit the global temperature increase to 1.5 degrees Celsius by mid-century. The Chinese government has been actively involved in this shared cause and made announcement of its NDCs — to achieve carbon peaking by 2030 and carbon neutrality by 2060. 07

Genor Biopharma is closely monitoring the emerging trends of climate change and relevant regulatory policies, and continuously evaluates its impact on environment from business activities, its energy efficiency and the options for energy saving and emission reduction.

- Reduce Energy and Emissions
- Define Resource Needs for Carbon Reduction
- Refine Processes to Enhance Resource Efficiency
- Consistent Standards to Propel Environmental Management



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# **Reduce Energy and Emissions**

As a biotech company, the Group consumes electricity, steam and water in the process of R&D and manufacturing, and involves biological activities and the use of hazardous chemicals. Our laboratories and manufacturing facilities generate waste gas, general solid waste and hazardous waste in daily operations, and also discharge wastewater. We ensure efficient use of resources with tightly monitored and controlled procedures and dispose of harmful factors appropriately before discharge.

Genor attaches great importance to the risks and opportunities brought by climate change, and understands that climate change may lead to loss of enterprise asset value, disruption of supply chain, increase in maintenance expenses and investment costs for adaptation measures, as well as the impact on corporate reputation resulting from challenged ability of continuous medicine supply. Taking into account of its stage of development and degree of impact on environment, the Group announced five environment-related targets and relevant pathways in 2021. During the Reporting Period, all relevant actions made phased progress, however, due to the reduction in the total number of employees, all intensity related measurements were increased.



- By 2025, to contrive carbon emissions reduction plans to reduce GHG emission intensity
- By 2025, to increase energy efficiency, promptly explore the use of clean energy, and reduce indirect energy consumption intensity
- By 2025, to enhance the efficiency of resource use, reduce the waste of water resources, and gradually reduce the water consumption intensity
- By 2025, to improve the waste utilisation rate, further develop intelligent and green office, and strive to reduce non-hazardous waste intensity
- By 2025, to promote innovative technologies and refined treatments to reduce the hazardous waste intensity



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Greenhouse Emissions	Unit	2022	2021
Direct GHG Emissions (Scope 1)	tCO <sub>2</sub> e	17.95	20.51
Energy Indirect GHG Emissions (Scope 2)	tCO <sub>2</sub> e	6,173.53	7,928.42
Total GHG Emissions (Scope 1&2)	tCO <sub>2</sub> e	6,191.48	7,948.57
Total GHG Emission Intensity	tCO₂e/Average Number of Employees	14.47	12.40

Notes:

- 1. The increase in emission intensity is mainly due to the reduction in the total number of employees following the organisational restructuring in 2022.
- 2. All intensity calculations are based on average number of employees.



# Define Resource Needs for Carbon Reduction

Our manufacturing activities are mainly at Yuxi production site, supporting the manufacturing of commercial medicines and preparing of clinical products that are independent-developed and through licensed-in arrangement. During the year, the Group's clinical products manufacturing capability in Shanghai was transferred to Yuxi complementing its business and organisational optimisation strategies.

# **Energy Needs and Usage**

The main manufacturing processes include cell recovery and culture, protein extraction and purification, formulation filling and packaging of finished products, which require mainly electricity, with fuel consumption for generator sets and vehicles. Our R&D, formulation and quality testing laboratories use various instruments powered by electricity, and the heating, ventilation and air conditioning equipment in the laboratories need to operate all day long to meet environmental requirements such as temperature and humidity. Our own warehouses are compliant with the storage requirements and conditions for drugs and materials, where the refrigerators and air conditioning systems are powered by purchased electricity. The Group continues to improve its warehouse management protocols and transportation efficiency to reduce resource use and emissions during the warehousing and logistics processes.

The Group abides by the *Energy Conservation Law of the People's Republic of China*, and has developed the *Operating Procedures for Production Planning* to make energy usage plans and assess the efficiency of usage, and conducts regular monitoring of resource consumption and make timely improvements as and when necessary.

Type of Energy	Unit	2022	2021
Diesel	MWh	2.62	2.96
Gasoline	MWh	65.39	78.55
Purchased Electricity	MWh	10,644	11,940
Purchased Steam	MWh	2,351	2,503
Total Energy Consumption	MWh	13,063	14,525
Total Energy Consumption Intensity	MWh/Average Number of Employees	30.52	22.66

*Note:* The increase in total energy consumption intensity is mainly due to the reduction in the total number of employees following the organisational restructuring in 2022.

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#### Water Resource Needs and Usage

The water resources needed for the Group's business activities are from the municipal water supply network at the operating sites, and are mainly used for cleansing of manufacturing equipment and laboratory instruments, as well as purified water and water for injection as preparations in the pharmaceutical process. There is no issue in sourcing water that is fit for our manufacturing process.

During the manufacturing process, the portable water we purchased is purified by distillation, ion exchange, reverse osmosis and ultrafiltration, and then distributed through a closed pipeline system to the designated points of use in the plant as solvent, injection and infusion fluids and laboratory water for pharmaceutical preparations.

In the processes of new drug development and manufacturing, the production equipment, testing instruments and apparatus need to be cleansed, such as CIP online cleaning systems for lyophilizers and storage tanks and temperature control of condensate equipment, to deliver compliant operation and ensure product quality.

The Group assigned relevant teams to develop a water consumption plan based on thorough calculation of water requirements for the engineering and production processes, thereafter, the water usage is regularly collected and analysed for improved efficiency. We recycle water used in production process where possible and the steam condensate generated from water production, such recycled water is used for campus gardens. The amount of water recycled accounts for approximately 10% of the Group's total water consumed, which was 93,100 tonnes in 2022.

Water Resource Management	Unit	2022	2021
Total Water Consumption	Tonne	93,100	87,763
Total Water Consumption Intensity	Tonne/Average Number of Employees	217.52	136.92

*Note:* The increase in total water consumption intensity is mainly due to the reduction in the total number of employees following the organisational restructuring in 2022.

# Refine Processes to Enhance Resource Efficiency

The Group evaluates energy usage in the manufacturing process, whereby energy-saving equipment and automated control systems are adopted for optimal efficiency in resource use, so as to reduce the overall energy waste and environmental impact.

Due to high yield and media efficiency, the group has applied self-developed continuous perfusion process to produce same amount of protein with a much smaller bioreactor than the industry average of 500L. GB261 (CD20/CD3, BsAb) reached a high potency of 6g/L expression, while GB263T (EGFR/cMET/cMET, TsAb) achieved a high expression level of 7g/L and high purity of 99.5%. With such productivity, the Group has not only created a high recovery rate, but also reduced the space occupied by the culture tank plant, as well as saving electricity and water consumption, achieving a perfect alignment of cost and resource efficiency.

Our registered and clinical drugs require proper and safe packaging, which amounted to a total of 5.36 tonnes in 2022. The external packaging materials for Jiayoujian 佳佑健<sup>®</sup> used environmentally friendly ink, glue and matte film.

Packaging Materials	Unit	2022	2021
Packaging Box/Carton	Tonne	0.38	0.10
Glass Bottle	Tonne	2.08	1.62
Rubber Plug	Tonne	2.90	_
Total Packaging Material Consumption	Tonne	5.36	1.72
Total Packaging Material Consumption Intensity	Tonne/Average Number of Employees	0.01	0.003



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# **Consistent Standards to Propel Environmental Management**

The Group is in strict compliance with the applicable laws and regulations of China, including the Environmental Protection Law, the Biological Safety Law, the Work Safety Law, the Special Equipment Safety Law, the Air Pollution Prevention and Control Law, the Water Pollution Prevention and Control Law, the Solid Waste Pollution Prevention and Control Law, the Regulations on the Safe Management of Hazardous Chemicals, and other relevant local and industry regulations in conducting its business activities. Our GMP certified production site in Yuxi, Yunnan province has developed an EHS management system, including the EHS Manual, the Procedures for Environmental Protection Management Control among other internal policies and operation procedures, which are instrumental in ensuring the proper application of technologies and methods for the discharge of exhaust gas, wastewater and waste.

On 28 February 2022, our production site completed a GMP compliance inspection for the manufacturing of Jiayoujian 佳佑健<sup>®</sup> (GB242, Infliximab). During the year, the Group also established an EHS Management Committee which has the management authority on environmental health and safety matters.

# Waste Gas Management and Emissions

The Group's production workshops and laboratories are equipped with air conditioning purification systems for air exchange and exhaust to maintain the air quality of the working environment. The fugitive waste gas from production workshops is treated through primary and intermediate air screening procedures, and the waste gas emitted from the laboratories is discharged through inspection ports and activated carbon adsorption devices that are connected to the discharge port to ensure compliance with the standards. The activated carbon is replaced regularly, and the used ones are handed over to gualified third-party service providers for further treatment.

In addition to our own monitoring and management of emissions, we also engage third-party professional environmental assessment organisations to measure and report on pollutant emissions on a regular basis. During the Reporting Period, the Group's laboratories and production site did not spot any exhaust emissions that are in violation or non-compliant.

Exhaust Gas Emissions	Unit	2022	2021
Nitrogen Oxides (NO <sub>x</sub> )	Kilogram	2.63	8.06
Sulphur Oxides (SOx)	Kilogram	0.12	0.13
Particulate Matter	Kilogram	0.19	0.98
Volatile Organic Compound (VOC)	Kilogram	55.99	_

#### Waste Management

The waste generated by the Group is divided into hazardous waste and non-hazardous waste. Hazardous waste mainly refers to laboratory waste liquids, end-of-life reagents, and waste reagent glass bottles. Non-hazardous waste includes packaging bags, cartons, glass bottles, external packaging cartons and office waste generated from production and laboratories.

The Group has formulated policies and operation procedures such as the Procedures for the Management of Hazard Source Identification, Evaluation and Control, the Hazard Waste Operating Procedures for Liquid and Solid Waste, the Standards for the Treatment and Disposal of Hazardous Waste, and the Operating Procedures for the Management of Hazardous Chemicals, to identify and prevent safety hazards caused by waste in a timely manner and dispose of waste properly.



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Hazardous Waste

We refine the classification of hazardous waste and require all relevant departments to transport, use and store them closely following required procedures. The departments in charge perform regular inventory, monitoring and inspection. Hazardous waste generated from production and laboratories is handed over to qualified third-party professional service providers for harmless treatment on a regular basis. In 2022, the total amount of hazardous waste was 13.73 tonnes. Since inception, the Group has not experienced any environmental pollution incidents.

Hazardous Waste	Unit	2022	2021
Total Hazardous Waste	Tonne	13.73	11.54
Total Hazardous Waste Intensity	Tonne/Average Number of Employees	0.03	0.02

#### Non-Hazardous Waste

We sort, store and dispose of non-hazardous waste in accordance with the management requirements of the local government, and have it handed over to environmental protection companies for treatment regularly. At the same time, we encourage all departments to take measures to reduce waste, and promote reuse and recycling in order to reduce the pressure of non-hazardous waste disposal and pollution to the environment.

Non-Hazardous Waste	Unit	2022	2021
Total Non-hazardous Waste	Tonne	242	246
Total Non-hazardous Waste Intensity	Tonne/Average Number of Employees	0.57	0.38

# Wastewater Discharge

The Group's wastewater is mainly generated from cleaning and processes of pharmaceuticals manufacturing, as well as waste reagents and wastewater generated from laboratory reagents, test solutions and instrument cleansing.

We have categorised the wastewater generated from the production process. The discharge of general wastewater is directly integrated into the municipal wastewater treatment system, while waste liquids with active cells, culture solutions and equipment cleansing liquids are treated by high temperature inactivation through kill tanks. Acid and alkali waste liquids used in production and laboratories need to be neutralised and diluted for disposal according to the *Operating Procedures for Laboratory Safety Management*. Under the premise of meeting regulatory requirements, we reuse the lye solution in the production process for multiple systems to reduce lye discharge.

The Group obtained a Pollutant Discharge Permit in 2021, and continued to monitor anions, total nitrogen and total phosphorus in wastewater, and implemented online monitoring of ammonia nitrogen, acidity and chemical oxygen demand, and maintained data synchronisation with the monitoring stations of the Environmental Protection Bureau to ensure data transparency and timeliness. During the year, the Group discharged a total of 29,130 tonnes of wastewater, representing a decrease of 35.8% year-on-year, mainly due to a drop in production activities as a result of the pandemic in the first half of the year.

Wastewater Discharge	Unit	2022	2021
Wastewater Discharge	Tonne	29,130	45,400
Chemical Oxygen Demand (COD)	Tonne	0.02	0.03
Biochemical Oxygen Demand (BOD)	Tonne	—	0.02
Ammonia Nitrogen	Tonne	0.001	0.02
Total Nitrogen	Tonne	0.006	—

# APPENDIX

# **HKEX ESG Reporting Guide Content Index**

ubject Areas, Aspects, Disclosures and KPIs		Sections/Declaration
	Aspect A1: Emissions	
General Disclosure	<ul> <li>Information on:</li> <li>(a) the policies; and</li> <li>(b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to exhaust gas and GHG emissions, discharges into water and land, and generation of hazardous and non-hazardous waste.</li> </ul>	Part 7 > Reduce Energy and Emissions Consistent Standards to Propel Environmenta Management
KPI A1.1	The types of emissions and respective emissions data.	Part 7 > Consistent Standards to Propel Environmental Management
KPI A1.2	Direct (Scope 1) and energy indirect (Scope 2) GHG emissions in total (in tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility).	Part 7 > Define Resource Needs for Carbon Reduction
KPI A1.3	Total hazardous waste produced (in tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility).	Part 7 > Consistent Standards to Propel Environmental Management
KPI A1.4	Total non-hazardous waste produced (in tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility).	Part 7 > Consistent Standards to Propel Environmental Management
KPI A1.5	Description of emission target(s) set and steps taken to achieve them.	Part 7 > Reduce Energy and Emissions
KPI A1.6	Description of how hazardous and non-hazardous wastes are handled, and a description of reduction target(s) set and steps taken.	Part 7 > Consistent Standards to Propel Environmental Management
	Aspect A2: Use of Resources	
General Disclosure	Policies on the efficient use of resources, including energy, water and other raw materials.	Part 7 > Define Resource Needs for Carbon Reduction
KPI A2.1	Direct and/or indirect energy consumption by type in total (kWh in '000s) and intensity (e.g., per unit of production volume, per facility).	Part 7 > Define Resource Needs for Carbon Reduction
KPI A2.2	Water consumption in total and intensity (e.g., per unit of production volume, per facility).	Part 7 > Define Resource Needs for Carbon Reduction
KPI A2.3	Description of energy use efficiency target(s) and steps taken to achieve them.	Part 7 > Reduce Energy and Emissions
KPI A2.4	Description of whether there is any issue in sourcing water that is fit for purpose, water efficiency target(s) set and steps taken to achieve them.	Part 7 > Define Resource Needs for Carbon Reduction
KPI A2.5	Total packaging material used for finished products (in tonnes) and, if applicable, with reference to per unit produced.	Part 7 > Refine Processes to Enhance Resour Efficiency

ubject Areas, Aspects, Disclosures and KPIs	Description	Sections/Declaration
	Aspect A3: The Environment and Natural Resources	
General Disclosure	Policies on minimising the issuer's significant impact on the environment and natural resources.	Part 7 > Define Resource Needs for Carbon Reduction
KPI A3.1	Description of the significant impacts of activities on the environment and natural resources and the actions taken to manage them.	Part 7 > Reduce Energy and Emissions Define Resource Needs for Carbon Reduction
	Aspect A4:Climate Change	
General Disclosure	Policies on identification and mitigation of significant climate-related issues which have impacted, and those which may impact, the issuer.	Part 2 > Board Statement Part 7 > Climate Change Risk
KPI A4.1	Description of the significant climate-related issues which have impacted, and those which may impact, the issuer, and the actions taken to manage them.	Part 7 > Reduce Energy and Emissions
	Aspect B1: Employment	·
General Disclosure	<ul> <li>Information on:</li> <li>(a) the policies; and</li> <li>(b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to compensation and dismissal, recruitment and promotion, working hours, rest periods, equal opportunity, diversity, anti-discrimination, and other benefits and welfare.</li> </ul>	Part 6 > Employment Practices
KPI B1.1	Total workforce by gender, employment type (e.g. full-or part-time), age group and geographical region.	Part 6 > Employment Practices
KPI B1.2	Employee turnover rate by gender, age group and geographical region.	Part 6 > Employment Practices
	Aspect B2:Health and Safety	
General Disclosure	<ul> <li>Information on:</li> <li>(a) the policies; and</li> <li>(b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to providing a safe working environment and protecting employees from occupational hazards.</li> </ul>	Part 6 > Production Safety and Occupational Healt
KPI B2.1	Number and rate of work-related fatalities occurred in each of the past three years, including the reporting year.	Part 6 > Production Safety and Occupational Healt
KPI B2.2	Lost days due to work injury.	Part 6 > Production Safety and Occupational Healt
KPI B2.3	Description of occupational health and safety measures adopted, and how they are implemented and monitored.	Part 6 > Production Safety and Occupational Healt

Subject Areas, Aspects, Disclosures and KPIs	Description	Sections/Declaration
	Aspect B3:Development and Training	
General Disclosure	Policies on improving employees' knowledge and skills for discharging duties at work. Description of training activities.	Part 6 > Staff Training and Development
KPI B3.1	The percentage of employees trained by gender and employee category (e.g., senior management, middle management).	Part 6 > Staff Training and Development
KPI B3.2	The average training hours completed per employee by gender and employee category.	Part 6 > Staff Training and Development
	Aspect B4: Labour Standards	
General Disclosure	<ul> <li>Information on:</li> <li>(a) the policies; and</li> <li>(b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to preventing child and forced labour.</li> </ul>	Part 6 > Employment Practices
KPI B4.1	Description of measures to review employment practices to avoid child and forced labour.	Part 6 > Employment Practices
KPI B4.2	Description of steps taken to eliminate such practices when discovered.	Part 6 > Employment Practices
	Aspect B5: Supply Chain Management	
General Disclosure	Policies on managing environmental and social risks of the supply chain.	Part 4 > Resilient Value Chain with Suppliers
KPI B5.1	Number of suppliers by geographical region.	Part 4 > Resilient Value Chain with Suppliers
KPI B5.2	Description of practices relating to engaging suppliers, number of suppliers where the practices are being implemented, and how they are implemented and monitored.	Part 4 > Resilient Value Chain with Suppliers
KPI B5.3	Description of practices used to identify environmental and social risks along the supply chain, and how they are implemented and monitored.	Part 4 > Resilient Value Chain with Suppliers
KPI B5.4	Description of practices used to promote environmentally preferable products and services when selecting suppliers, and how they are implemented and monitored.	Part 4 > Resilient Value Chain with Suppliers

ubject Areas, Aspects, Disclosures and KPIs	Description	Sections/Declaration
	Aspect B6: Product Responsibility	
General Disclosure	<ul> <li>Information on:</li> <li>(a) the policies; and</li> <li>(b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to health and safety, advertising, labelling and privacy matters relating to products and services provided and methods of redress.</li> </ul>	Part 4
KPI B6.1	Percentage of total products sold or shipped subject to recalls for safety and health reasons.	During the Reporting Period, no products or services sold or shipped by the Group experienced recall for safety and health reasons.
KPI B6.2	Number of products and service-related complaints received and how they are dealt with.	Part 4 > Quality Assurance System
KPI B6.3	Description of practices relating to observing and protecting intellectual property rights.	Part 3 > Innovative Strength Expediting Intellectual Property Rights Accumulation
KPI B6.4	Description of quality assurance process and recall procedures.	Part 4 > Quality Assurance System
KPI B6.5	Description of consumer data protection and privacy policies, and how they are implemented and monitored.	Part 3 > Clinical Trials Progressing with Speed
	Aspect B7: Anti-Corruption	
General Disclosure	<ul> <li>Information on:</li> <li>(a) the policies; and</li> <li>(b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to bribery, extortion, fraud and money laundering.</li> </ul>	Part 2 > Compliance Management
KPI B7.1	Number of concluded legal cases regarding corrupt practices brought against the issuer or its employees during the reporting period and the outcomes of the cases.	Part 2 > Compliance Management
KPI B7.2	Description of preventive measures and whistle-blowing procedures, how they are implemented and monitored.	Part 2 > Compliance Management
KPI B7.3	Description of anti-corruption training provided to directors and staff.	Part 2 > Compliance Management
	Aspect B8: Community Investment	
General Disclosure	Policies on community engagement to understand the needs of the communities where the issuer operates and to ensure its activities take into consideration the communities' interests.	Part 6 > Community Building
KPI B8.1	Focus areas of contribution (e.g., education, environmental concerns, labour needs, health, culture, sport).	Not applicable
KPI B8.2	Resources contributed (e.g., money or time) to the focus area.	Not applicable