GENOR
BIOPHARMA

GENOR BIOPHARMA HOLDINGS LIMITED

(Incorporated in the Cayman Islands with limited liability)

Stock Code: 6998

2024

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

Contents

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About this Report

Genor Biopharma Holdings Limited (the "Company", together with its subsidiaries hereinafter referred to as "the Group", "Genor" or "We") has prepared this 2024 Environmental, Social and Governance ("ESG") Report in accordance with the Environmental, Social and Governance Reporting Guide (the "Reporting Guide"), which is contained in Appendix C2 to the Rules Governing the Listing of Securities (the "Listing Rules") on the Stock Exchange of Hong Kong Limited ("HKEX"). This report follows the reporting principles of Materiality, Quantitative, Balance and Consistency as well as the Reporting Boundary in respect of collecting relevant materials, analyzing 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 2024 to 31 December 2024 (the "Reporting Period"). Unless otherwise specified, the information and data in this report are consistent with the scope of the Group's financial report, and the report covers the Group's principal operating entities during the Reporting Period, including Genor Biopharma Co., Ltd. ("Genor Biopharma") and the San Francisco-based Ab Therapeutics Inc. ("ABT").

Data and Information Sources

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

Data Reliability

This report was reviewed by the Group's management and approved by the Board of Directors (the "Board") on 28 March 2025. The Group is responsible for the authenticity, accuracy and completeness of the content in this 2024 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 2024 Annual Report, the 2024 Annual Report shall prevail.

Publish and Access

The Report is published on the website of the HKEX (www.hkexnews.hk) and the website of the Company (www.genorbio.com) for viewing and downloading.

Message From the Chief Executive Officer

In 2024, Genor continued to advance with the mission of 'providing innovative treatments for patients in need'.

During the Reporting Period, the National Health Commission ("NHC") alone with other relevant government agencies has introduced a number of 'hardcore' policy initiatives to promote the research and development of world-leading innovative medicines in China ("Global New") which boosted the development of the biomedical industry, and supported small and medium-sized pharmaceutical enterprises to alleviate the difficulties in their international development.

Promoting the development of "Global New" is aligned with Genor's strategic direction of focusing on developing targets and projects that are highly innovative and with Best-in-Class ("BIC") potential. While firmly implementing the core strategy of "Focusing, Optimizing, Accelerating and Expanding" in 2024, Genor continued to accelerate the registration and clinical trial projects, and gained progress in the international expansion of our innovative products.

In terms of accelerating product registration, the new drug application ("NDA") for Genor's highly differentiated oral CDK4/6 inhibitor, GB491 ("Lerociclib"), in combination with Fulvestrant for the treatment of hormone receptor ("HR") -positive and human epidermal growth factor receptor 2 ("HER2") -negative ("HR+/HER2-") locally advanced or metastatic breast cancer patients (second-line treatment for advanced breast cancer) with disease progression following previous endocrine therapy is about to be approved for market, and we have been pressing ahead with the NDA of GB491 in combination with Letrozole for the treatment of locally advanced or metastatic HR+/HER2- breast cancer (first-line treatment for advanced breast cancer) that had not received prior systemic antitumor therapy.

At the same time, we promoted several quality pipelines at international conferences, which have been positively recognized:

- The Independent Data Monitoring Committee ("IDMC") 's interim analysis of GB491 in a phase 3 first-line clinical trial was presented in the poster discussion session at the American Society of Clinical Oncology ("ASCO") annual meeting held in June 2024.
- Updated research data from a clinical trial study of GB263T (EGFR/cMET/cMET, TsAb) have been accepted by the European Society for Medical Oncology ("ESMO") Congress 2024 and were published on 14 September 2024.
- In terms of our early-stage pipelines, research abstracts of two tri-specific antibody molecule projects have been accepted for publication at the 2024 Annual Meeting of the America Association for Cancer Research ("AACR"). Among them, GB268 (anti-PD-1/VEGF/CTLA-4) entered the pre-investigational new drug ("pre-IND") enabling stage and Chemistry, Manufacturing and Controls ("CMC") process development in 2024, the preliminary results suggest that the tri-specific molecule has a good drug developability and stability. Its Good Laboratory Practice ("GLP") toxicology study in cynomolgus monkeys with weekly dosing for 4 weeks was completed in March 2025, with no serious drug-related adverse effects observed in animals after multiple doses. The preliminary CMC results suggest that the tri-specific molecule has a good drug developability and stability, and the pilot-scale Good Manufacturing Practice ("GMP") production have been completed.

Dr. GUO Feng
Chief Executive Officer

In 2024, Chinese biopharmaceutical innovation enterprises were very active in cross-border mergers and acquisitions, and business cooperations. Meanwhile, the forms of biotechnology transactions, the therapeutic areas covered, and the technology fields has been more diverse. By introducing overseas funds with the NewCo model, building an international management team, and serving Chinese high-quality innovative biomedical products to global patients in a more flexible and effective way, Genor, again, acted as a pioneer of Chinese biomedical innovation enterprise, and explored a significant path for domestic innovative drugs to go abroad.

- In August 2024, Genor entered into a license agreement (the "License Agreement") and a stock purchase agreement (the "Stock Purchase Agreement") with TRC 2004, Inc. (a company co-founded by Two River, LLC and Third Rock Ventures in Delaware, the United States of America). Under the License Agreement, the Group has agreed, among others, to grant TRC 2004, Inc. an exclusive worldwide license (excluding mainland China, Hong Kong, Macau and Taiwan) to develop, use, manufacture, commercialize and otherwise exploit GB261 (CD20/CD3, BsAb). The collaboration between the parties will mainly focus on exploring the potential of GB261 (CD20/CD3, BsAb) in autoimmune diseases.

- Thus, GB261 (CD20/CD3, BsAb) got the opportunity to expand the international market and successfully go aboard after it received global academic recognition at the 65th Annual Meeting of the American Society of Hematology ("ASH") in December 2023.

Genor has been actively carried out innovative initiatives in external cooperation and expansion. On 13 September 2024, we entered into a merger agreement (the "Merger Agreement") with Edding Group Company Limited ("Edding"). Through the deep integration of research and development, sales, production, finance and other aspects, both parties are expected to give full play to the complementary advantages of both sides in innovation, research and development and business capabilities, and to achieve the two-way empowerment of 'R&D-driven' and 'product commercialization'. In this way, Genor and Edding will strive to achieve the rapid commercial expansion of the breast cancer treatment drug Lerociclib which is about to be approved for market, to achieve the continuous output of early quality pipeline products through the advanced antibody technology platform, and to enhance the overall market competitiveness of the Group. This merger would also provide a reference for the innovation ecology and upgrading development of China's biomedical industry.

All these results have been achieved thanks to the joint efforts of Genor's management and all employees, who have demonstrated extraordinary creativity, dedication and professional integrity in a challenging environment during the year.

What's past is prologue. Seeing a very promising future that Genor has already presented, I believe that with merger between Genor and Edding well underway, the NDA approval of Lerociclib and the acceleration of various early research and clinical projects, the Group will usher in new development opportunities and momentum for development. Throughout our journey, Genor would realize the growth potential through innovation, and stay committed to serving patients in China and around the world.

02

Environmental, Social and Governance Strategy

Group Overview

Genor believes that social well-being encompasses the entitlement of individuals to healthy life. Since the establishment of the Group in 2007, we have focused on urgent but unmet needs of Chinese and global patients in the fields of oncology and immunology, striving to build an innovation-driven company with capabilities in drug discovery, preclinical research, clinical development, drug registration, and CMC development.

The Group initiated its development strategy of "Focusing, Optimizing, Accelerating and Expanding" in 2022 and made steady progress in 2023. We have continued to implement this strategy in 2024 to proactively respond to the increasingly complex macroeconomic environment and challenges in the biopharmaceutical industry, as well as to fully explore and persistently pursue new opportunities by building an agile organisation and maintaining efficient operations.

During the Reporting Period, the Group further optimised its structure, realizing the asset-light model through various flexible forms of external cooperation, thereby significantly reducing operating costs. With the initiatives of lowing costs and improving efficiency, we have also carried out strategic cooperation and established several pipeline commercial expansion partnerships, focusing on advancing of our core pipeline and the approval of new drugs. In particular, Genor entered into an agreement with Edding on 13 September 2024, whereby the Company will acquire Edding by way of a merger. The completion of this agreement is expected to fully leverage complementary strengths of the two companies to create synergies building stronger Research & Development ("R&D") and Product Marketing & Sales capacity, unleashing combined potentials and competitiveness in the market. In this way, the Group will bring innovative medicine and therapy to patients in an accelerated speed.

We are committed to adhering medical ethics and compliant operations. We respect our team and value the contribution of each to our open and inclusive culture that enables performance excellence. This help forge the very essence of the Group's sustainable development.

Our mission anchored in providing innovative treatments for patients in need

2024 Highlights

Persisting in the Group's core strategy of 'Focusing, Optimizing, Accelerating and Expanding', Genor has achieved many milestones in 2024 in different aspects such as promoting registration and clinical trials, gaining global recognition of clinical results, global expansion and strategic cooperation.

Efficient registration and clinical trials

GB491 (Lerociclib, a differentiated oral CDK4/6 inhibitor)

- The NDA progresses of GB491 in combination with letrozole for the treatment of locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2-negative ("HR+/HER2-") breast cancer (first-line treatment for advanced breast cancer) that had not received prior systemic antitumor therapy:
  - 28 February 2024, the Group submitted the NDA to the National Medical Products Administration ("NMPA").
  - 13 March 2024, the NDA was officially accepted.
  - September 2024, on-site clinical inspection was completed.
  - December 2024, feedback on NDA queries was submitted.

- Following the formal acceptance of the NDA of GB491 in combination with Fulvestran for the treatment of HR+/HER2- locally advanced or metastatic breast cancer patients (second-line treatment for advanced breast cancer) with disease progression following previous endocrine therapy by NMPA on 28 March 2023, and on-site clinical inspection that was successful completed on 31 August 2023:
  - March 2024, feedback in response to NDA queries was submitted.
  - May 2024, the drug testing at the China National Institutes for Food and Drug Control ("NIFDC") was completed.
  - September and October 2024, the overseas on-site pre-approval inspections on the Active Pharmaceutical ingredient ("API") and drug product plants were completed.
  - December 2024, the reports for follow-up items and related materials were submitted to the Center for Food and Drug Inspection ("CFDI") under NMPA.

GB261 (CD20/CD3, BsAb)

  - July 2024, the clinical study report of phase I/II clinical trial for lymphoma was completed.

International recognition of the clinical results

GB491 (Lerociclib, a differentiated oral CDK4/6 inhibitor)

- The results of the interim analysis for first-line phase III clinical trials were presented in the poster session at the ASCO annual meeting in June 2024.
  - The IDMC has conducted efficacy and safety data evaluation on the interim analysis of the phase III clinical trial of Lerociclib in combination with letrozole as the first-line treatment for advanced breast cancer. The IDMC recommended that this clinical trial had met the prespecified requirement of statistical significance in efficacy for the interim analysis with good safety and tolerance.

GB263T (EGFR/cMET/cMET, TsAb)

- These updated research data have been accepted by the ESMO Congress 2024 and were published on 14 September 2024.
  - As of 31 December 2023, a total of 15 patients had received at least one GB263T (EGFR/cMET/cMET, TsAb) treatment. All patients had received previous third-generation EGFR-TKI and platinum-based chemotherapy and the median number of prior lines of systemic therapy was 3.

R&D of the Global Innovative New Drugs

- Abstracts of two TsAb molecule projects have been accepted for publication at the 2024 Annual Meeting of the AACR.

- As of 31 December 2024, multiple development of bi-poly antibody molecules at or near the PCC stage have been completed, all of which are highly innovative bi-specific/multi-specific antibody projects with the potential to be BIC.

- In 2024, GB268 (anti-PD-1/VEGF/CTLA-4) entered the pre-IND enabling stage and conducted the CMC process development and GLP toxicology study. The preliminary results suggest that the tri-specific molecule has good drug developability and stability, and no significant drug related toxicity has been observed in the high, medium and low dose groups of the 4-week exploratory toxicological experiment in cynomolgus monkeys.

Successfully achieving innovation's going abroad

- On 2 August 2024, Genor entered into the License Agreement and the Stock Purchase Agreement with TRC 2004, Inc.
  - Under the License Agreement, the Group has agreed, among others, to grant TRC 2004, Inc. an exclusive worldwide license (excluding mainland China, Hong Kong, Macau and Taiwan) to develop, use, manufacture, commercialize and otherwise exploit GB261 (CD20/CD3, BsAb). The collaboration with TRC 2004, Inc. will mainly focus on exploring the potential of GB261(CD20/CD3, BsAb) in autoimmune diseases.
  - The successful exploration of GB261(CD20/CD3, BsAb) in the global market reflects the recognition of Genor's new drug development and innovation pipeline by world-class biotechnology investment institutions and management teams.

Milestones of strategic cooperations

- On 19 January 2024, Genor entered into a technology transfer agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd ("Zhongmei Huadong"), under which the Group's anit-FGFR2b molecular sequences, technical data and related intellectual property ("IP") rights were transferred to Zhongmei Huadong.

- Genor entered into the Merger Agreement with Edding on 13 September 2024, whereby the Group will acquire Edding by way of a merger, and in consideration therefor, the Company will allot and issue shares to the shareholders of Edding.
  - Through the deep integration of research and development, sales, production, finance and other aspects, both parties are expected to achieve the two-way empowerment of 'research and development-driven' and 'product commercialization' to boost market competitiveness.
  - The commercial operation capability and market experience of Edding will provide strong support for the early-stage R&D and Genor's rapid advancement of clinical pipeline, accelerate the progresses of the corresponding indication projects in the Group's pipeline, shorten drugs' pre-market cycle, and bring high quality treatment options to patients more efficiently.

ESG Governance

Materiality Assessment

Stakeholder Engagement

Genor has maintained effective engagement with stakeholders, exchanging views on critical issues that cover business operations and future growth challenges in an honest and transparent manner. This also includes regular progress updates on agreed key performance indicators during daily business activities. Our stakeholders include government and regulatory bodies, investors, employees, suppliers and partners, whose feedback and expectations are duly reviewed and responded to as such that we deliver our sustainable growth balancing competing priorities. During the Reporting Period, we assessed the effectiveness of various communication channels to ensure that material ESG topics were properly identified and validated, hence reflected in the preparation of this report.

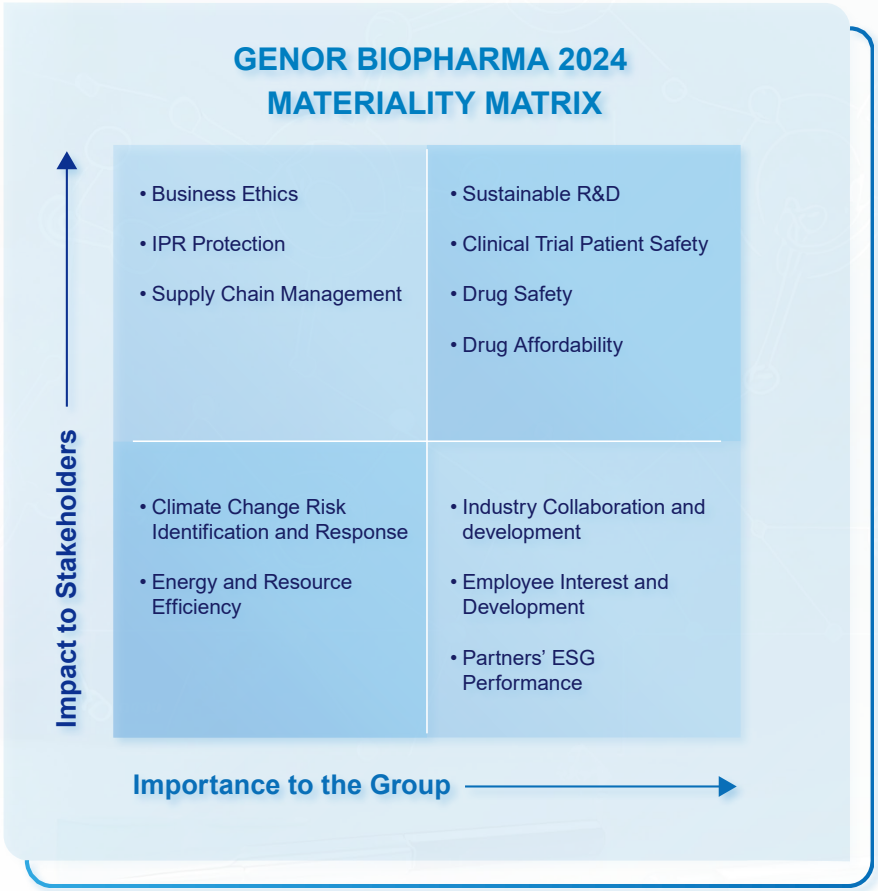
Stakeholder	Topics of Interest	Communication and Response
Shareholders and Investors	• Economic Efficiency • Compliance • Improve Corporate Governance • Transparency in Information Disclosure • Progress of R&D Pipeline and Clinical Projects • Globalisation Strategy	• Shareholder Meetings • Investor Meetings and Roadshows • Industry Summits • Press Releases and Announcements • Company Website Announcements • Annual and Interim Reports
Government and Regulatory Authorities	• Compliance • Transparency in Information Disclosure • Quality and Safety of Medicine and Services • Patient Rights and Privacy Protection	• Government – Enterprise Meetings • Seminars • Compliance Reports • Regular Information Disclosure
Customers (Hospitals, Pharmacies and Patients)	• Innovative Discovery and Clinical Pipeline Programs • Drug Indications, Efficacy, Quality and Safety • Intellectual Property Rights Protection • Subject Privacy Protection	• Drug Efficacy Disclosure and Communication • Customer Satisfaction • Customer Grievance Mechanism • Medication Instructions
Employees	• Employee Rights • Development and Training • Compensation and Benefits • Code of Conduct	• Cultivation of Corporate Culture • Employee Communication Mechanism • Staff Meetings • Employee Training
Suppliers and Other Partners	• Sustainable Supply Chain Management • Procurement Management • Partner Compliance • Resource Utilisation and Use Efficiency • Intellectual Property Rights Protection	• Supplier Introduction, Evaluation and Audit Mechanism • Procurement Management • Work Meetings • Annual Audit
Public and Media	• Health Literacy	• Press Releases and Announcements • Media Activities
Industry Association and other NGOs	• Quality and Safety of Products and Services • Compliance • Industry Collaboration and Development	• Industry Exhibition and Discussion • Company Website Information Releases • Company Reports

Materiality Validation and Prioritization

During the Reporting Period, the Group further refreshed its material issue universe which is reduced to 12 topics — a result arrived at with addition of the "Energy and Resource Efficiency" topic and the "ESG Performance of Partners" topic, and recategorization of "Climate Change Related Risk Identification and Response" from governance section to environmental section, to reflect the Group's reduced need for resources by its owned operations during the Reporting Period; and with removal of the topics of "Marketing Ethics", "Affordability of Pricing", "Safety Management of Laboratories" and "Hazardous Waste Disposal and management", which are no longer relevant following the Group's restructuring. This exercise also drew from our on-going communication with stakeholders and referenced, as a sustained protocol, the material topics of the Biotechnology and Pharmaceuticals Sector under Sustainability Accounting Standards Board ("SASB"), in the context of the Group's restructuring and acquisition agreement, as well as their implications to our existing and future business.

ENVIRONMENTAL	1 Climate Change Risk	2 Energy and Resource Efficiency	
SOCIAL	3 Sustainable R&D 4 Clinical Trial Patient Safety 5 Drug Accessibility	6 Drug Safety 7 Intellectual Property Rights ("IPR") Protection 8 Employee Interests and Development	9 Industry Collaboration and Development 10 Supply Chain Management
GOVERNANCE	11 Business Ethics	12 ESG Performance of Partners	

In accordance with the relevant requirements of Appendix C2 ESG Reporting Code to the Listing Rules, the Group mapped out all identified topics from the universe in a matrix, drawing from both their impacts to the stakeholders and importance to the Group. The prioritized topics in 2024 are sustainable R&D, clinical trial patient safety, drug safety and drug accessibility.



During the Reporting Period, Genor further focused its resources to advance early discovery and research projects and accelerate the pipeline of clinical trials. All investigational drugs were produced by CDMOs, as a result, the identification of climate change related risks and opportunities and the analysis of their relevant financial impacts, as well as impact to the environment in the context of the Group's owned business were largely lessened.

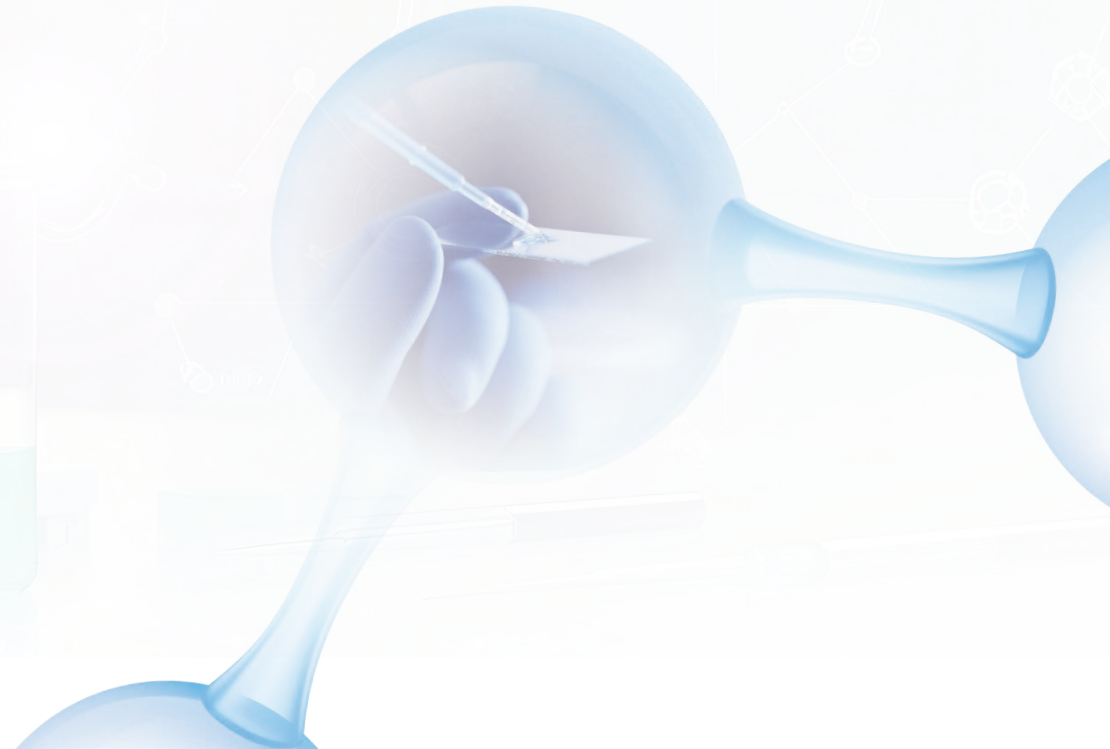
The materiality matrix and prioritization above were submitted to the Board with an approval made on 28 March 2025. This report is presented based on the priorities among other disclosure requirements.

Board Statement

The Board understands that global warming and biological degradation have profound impact to the well-being of humankind. Our attention to resource efficiency begins from R&D planning and is in close alignment with our goals of benefiting patients with our innovative drugs and treatments in China and globally. Good corporate governance is at the heart of the Group's sustainable development and value creation. We will, therefore, strengthen our governance framework and policies to integrate sustainability factors in the course of various decision-making processes to ensure alignment in our management actions whereby the expectations and concerns of the stakeholders are duly addressed.

As the highest decision-making body on sustainability, the Board holds the ultimate responsibility on the Group's strategy, risk management and disclosure on sustainability. It is also charged with the oversight on material topics identification and determination as well as progress monitoring on relevant areas. Over the past three years, the Group had been closely following the evolution of unmet medical needs and relevant regulatory regimes, and leveraged its efficiency in operations and strength of its team anchoring on its highly differentiated and innovative research pipelines. During the Reporting Period, the Group improved its decision-making efficiency in early discovery and accelerated the clinical pipelines, supported by successful transition to contracted development and manufacturing and further elevated quality control systems. This agility has enabled swift adaptability of the business to maximize enterprise value.

Following the business restructuring during the Reporting Period, the intensity indicators of several ESG KPIs, which is calculated with a further year-on-year reduced annualized number of full-time staff as the denominator, can hardly be useful for comparison purpose. Furthermore, Genor announced a material acquisition agreement which is expected, upon completion, to significantly propel pipeline advancement with a bolder NDA timeline so that we'll provide high quality alternative treatment choices even quicker to patients in China and abroad. Nevertheless, the proposed merger will suggest a redefinition of the Group's operational boundary and likely give rise to policy revisions and accountability streamlining in post transaction integration, including various sustainability targets and KPIs to appropriately reflect Genor's business scope and stage of development. The progress of any new initiatives will be reported in the coming year.



Compliance Management

Genor complies with the Listing Rules, and the applicable laws and regulations in countries where it operates. We continue to strengthen corporate governance and seek to conduct ourselves with standards higher than regulations. With a firm belief in business integrity, we remain vigilant on compliance and risk management.

The Group strictly complies with applicable laws and regulations in the People's Republic of China, such as the Company Law, the Securities Law, the Fair Competition Law, the Anti-money Laundering Law, and has employed internal policies and management system to ensure compliance. Regular reviews are conducted to assess the effectiveness of policy implementation and risk management. We offer onboarding and refreshment training on code of conduct and compliance awareness. During the Reporting Period, no prosecution against the Group or its employees on misconduct were received and there were no related on-going lawsuits.

Anti-Corruption Training

During the Reporting Period, the Group offered various on-line training programs including anti-corruption training. Special online training on anti-corruption for new joiners was arranged. At the same time, board directors are required to attend routine anti-corruption trainings. In 2024, the Group offered and completed a half-hour anti-corruption training to all directors and staff members.

Genor requires all full-time and advisory contract 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 and internal policies. Anti-bribery and anti-corruption are set as key performance indicators and included in performance appraisals to shape behaviours of all. We also require our suppliers and business partners to sign a written pledge and follow the same principles.

Whistleblowing Policy

The Group has made public a Whistleblowing Management Policy which provides clarity on the awareness of and the reporting mechanism for corruptive activities. It has also emphasized that any reported incident will be processed with independence and impartiality. We have a hotline in place facilitating employees and other stakeholders to report actual and suspected misconducts including but not limited to direct or indirect fraud, extortion, bribery and corruption, as well as violations of corporate policies, rules and ethics guidelines. Staff members are also encouraged to raise concern on controversial behaviors through additional channels as appropriate, such as their supervisors and the Human Resources Department.

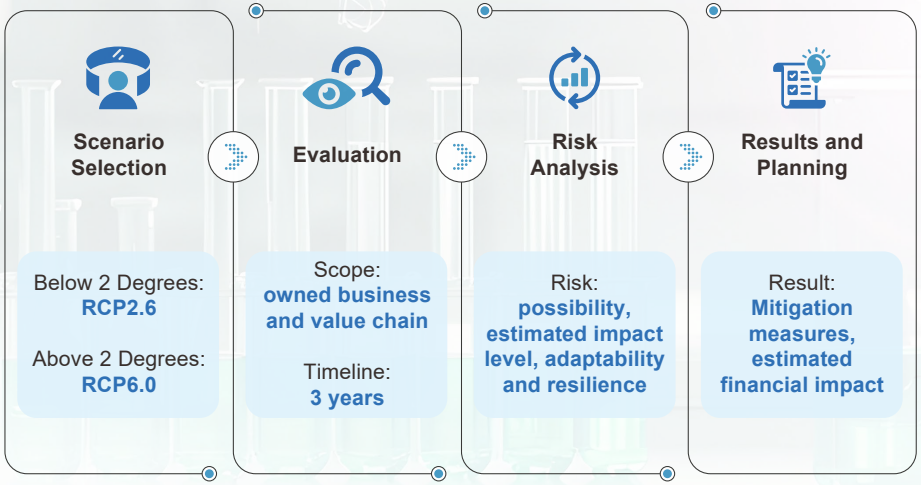
The Group's compliance team screens and dissects all issues reported, and proceeds to conduct independent investigations for eligible cases and produces investigation reports. We respect the confidentiality of whistleblowing process, and keep the reported matter, the identities of the whistle blower and the person being reported strictly confidential. We assess potential situations that may cause a conflict of interest in the process and make necessary abstention accordingly. 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.

Climate Risk and Opportunity

Climate change has been weakening the Ecosystem as such that human health and healthcare system are being negatively impacted. Despite that we are tasked to provide drugs and treatment to patients and address unmet medical needs, the whole healthcare industry contributes to 5% of global greenhouse gas emissions ("GHG").

During the Reporting Period, the Group's business activities, covering early discovery, clinical research and contracted manufacturing of investigational drugs, were conducted in an office environment. As a step of restructuring, the Group closed its Beijing office and R&D laboratory in Shanghai, closure of the latter was conducted abiding by relevant requirements on hazardous waste disposal. During the Reporting Period, Gener's GHG emissions were primarily from purchased electricity (Scope 2) and value chain activities (Scope 3).

Following the confirmation on business scope and sources of emissions, the Group conducted an exercise identifying and analyzing Climate change related risks and opportunities, as well as extrapolating their financial impact, based on the scenarios of RCP[1] 2.6 and RCP6.0 in line with the ESG Reporting Code to the Listing Rules.



We have established an initial list of climate related risks and opportunities, in which the physical and transition risks of owned business and assets were evaluated according to its type, scope and level of impact, as well as relevant mitigation plans. The results show that there is limited financial impact to the Group's business, nevertheless, mitigation plans will be executed, and on-going assessment and monitoring will be conducted.

The Group also evaluated the transition risks, including carbon tax, regulation evolution and low carbon technology application, and reached its conclusive view on direction of actions going forward. We will continue to accelerate the advancement of early discovery projects and clinical research programs, so that we can contribute to addressing the unmet needs of patients by providing approved drugs, at the same time, we'll leverage our strength in CMC to reduce product environmental footprint by way of resource optimization, in the context of energy transition. The Group will also monitor the policy on carbon tax and work with partners and peers to fight against the climate risk collectively.

[1] *RCP: Representative Concentration Pathway*

	Potential Impact	Impact Level	Financial Impact	Mitigation Measures
Physical Risk — Flood	Flood leads to loss of land, obstruction of transport, among others, hence may hinder the provision of investigational drugs, delay research projects or cause to revise research plan. There is always a post-flood threat of waterborne infectious epidemic outbreak. Once infected, the subjects, who participate trial programs on treatment of oncology and autoimmune diseases, may be obliged to change of treatment plan or a termination, resulting in poor therapeutic outcome and clinical data.	Low	The projected clinical research suspension and postponement would require more subjects, and clinical research project would require additional investment due to research data integrity failure. Additional expenses may occur resulting from extra resource put to ensure continued supply and logistics.	1. Strengthen our assessment on Contract Development and Manufacturing Organisation ("CDMO") partners' disaster recovery capabilities, raise our standards, monitor and enable their emergency handling capacity and disaster preparedness. 2. To build and synchronize emergency planning with CDMOs and other partners based on identified climate risks scenarios, and review annually. 3. Monitor disaster recovery plan of government agencies where we operate, to understand local priorities and handling procedures. 4. Proactively adapt clinical trial planning so that such potential failures are taken into consideration. 5. Collaborate with clinical trial project hosts in broader geographical spread so that subjects/ patients join the treatment program locally.
Physical Risk — Drought, extreme heat	The increased frequency and area affected by drought and extreme heat may lead to: lower groundwater table, shortage of water supply in cities and regional power failures. It also stresses human body worsening chronic conditions. As a result, the productivity of CDMO and partners will be lowered. The storage and transport of investigational products require temperature-controlled conditions; hence, relevant costs and defect rate may increase.	Low	Prices on resources, i.e. water and electricity may fluctuate, increasing operating expenses. Lower labor productivity may cause rise of hiring costs.	
Physical Risk — Typhoon	Tropical Cyclone may cause transportation disruption, flight delays, and threaten the safety of partners' production facility, hence, disrupt the manufacturing of investigational drugs, delay the regular hospital visits of the subjects/patients, leading to undesirable treatment outcome.	Low	Transportation cost may rise, preparations to resume product may require support in capital or otherwise, leading to increase in expense or capital expenditure. The deviation from standard care of subjects/ patients may lead to research data inaccuracy, consequently more resources and time are needed, and additional subjects to be recruited for the extended period of clinical trials.	

03

Sustained Innovation Yields Tangible Results

Genor has always focused its research and development on oncology and autoimmune diseases, to address unmet medical needs of patients in China and globally. We firmly implement our strategy of Focusing, Optimizing, Accelerating and Expanding, prioritizing projects that are highly innovative and with BIC potentials. We effectively promote the innovation of highly differentiated early-stage molecules and targets, step up efforts to efficiently advance key pipelines，accelerating the transformation of R&D results to benefit patients.

- Benchmarking the global frontier of early research innovation
- Accelerating the Clinical Pipeline Products with Critical Treatment Needs
- Continuously Strengthening the IP Management System

Benchmarking the Global Frontier of Early Research Innovation

Genor's R&D has always taken the potential global FIC/BIC as a primary consideration in determining the research direction and targets, ensuring the global competitiveness of the Group's pipeline products. We have several R&D projects that have been widely recognized around the world.

The Group monitors and actively adjusts the implementation plan to adapt to changes in regulatory requirements in the domestic and international markets to ensure smooth progress of relevant pipelines.

- We have carried out active communication with relevant regulatory agencies on the Notice of the National Medical Products Administration on the issuance of Optimizing the Pilot Work Plan for Innovative Drug Clinical Trials Review and Assessment issued in July 2024, timely evaluated the policy impact on the Group's project strategy and implementation schedules, and have accordingly improved preparation work for the following IND application, approval process and clinical research project.

- We have paid close attention on the Notice on Providing Advanced Services for Accepting Innovative Drugs and Varieties that Can Be Included in Priority Review and Approval Procedures or Conditional Approval Procedures upon Communication issued by the Center for Drug Evaluation ("CDE"), NMPA in October 2024, and keep updated on the national optimization measures and processes for clinical trials and marketing applications of innovative drugs, so as to improve the efficiency of our clinical product application and related registration plans.

As of 31 December 2024, we completed the development of several PCC molecules with great potential to turn into BIC bi-specific/multi-specific antibody projects. Among them, GB268 (anti-PD-1/VEGF/CTLA-4) entered the pre-IND enabling stage, and abstracts of two TsAb molecule projects, GB268 (anti-PD-1/VEGF/CTLA-4) and GBD218 (CD3/BCMA/GPRC5D) have been accepted for publication at the 2024 Annual Meeting of the AACR.

- GB268 (anti-PD-1/VEGF/CTLA-4) is an innovative tri-specific antibody solely developed by Genor, specifically targeting PD-1, CTLA-4 and VEGF, with a novel molecular design that balances the activity of different arms of the antibody. The pre-clinical results show that GB268 (anti-PD-1/VEGF/CTLA-4) can substantially enhance the anti-improve effect with a better safety profile compared to the combination of three monoclonal antibodies, namely PD-1, CTLA-4 and VEGF, as well as the anti-PD-1/VEGF or anti-PD-1/CTLA-4 BsAb. It has the potential to become an upgraded immune checkpoint inhibitor.

- In 2024, GB268 (anti-PD-1/VEGF/CTLA-4) entered the pre-IND enabling stage and conducted the CMC process development and GLP toxicology study. The preliminary results suggest that the tri-specific molecule has a good drug developability and stability, and no significant drug related toxicity has been observed in the high, medium and low dose groups of the 4-week exploratory toxicological experiment in cynomolgus monkeys.

Abstracts of two of the tri-specific antibody molecules have been accepted for publication at the 2024 AACR

Topic of "Single Target and Bispecific Antibodies", Number: PO.IM01.06

Title: "Development of GB268, a tri-specific antibody targeting PD-1/CTLA-4/VEGF, with enhanced efficacy and reduced toxicity in pre-clinical studies"

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Session PO.IM01.06 - Single Target and Bispecific Antibodies

2712 / 3 - Development of GB268, a tri-specific antibody targeting PD-1/CTLA-4/VEGF, with enhanced anti-tumor efficacy and reduced toxicity in pre-clinical studies

April 8, 2024, 1:30 PM - 5:00 PM | Section 6

Presenter/Authors

Q. Du, Y. Lv, J. Xu, F. Peng, H. Cao, X. Yang, Z. Qian, X. Li, Y. Cao, Q. Ding, Y. Tan, **S. Han**;
Genor Biopharma Co. Ltd., Shanghai, China

Disclosures

Q. Du, None..
Y. Lv, None..
J. Xu, None..
F. Peng, None..
H. Cao, None..
X. Yang, None..
Z. Qian, None..
X. Li, None..
Y. Cao, None..
Q. Ding, None..
Y. Tan, None..
S. Han, None.

Abstract

Background: Immunotherapy using immune checkpoint modulators such as anti-PD1/PD-L1 have been widely used in cancer therapy. Combination of checkpoint inhibition using anti-PD1 and anti-CTLA4 has improved therapeutic efficacy but is also accompanied by severe immune related adverse events (irAEs) which limited their clinical use. Bi-specific antibody targeting PD-1/CTLA-4 such as cadonilimab has shown improved clinical benefits with reduced irAEs in cervical cancer. Vascular endothelial growth factor (VEGF) is overexpressed in various solid tumors and anti-VEGF agents inhibit neovascularization and shrink tumor with time. Combined application of bevacizumab and PD-1/PD-L1 blockade displays durable and improved anti-tumor effects. We have recently developed a novel tri-specific antibody GB268, specifically targeting PD-1, CTLA-4 and VEGF with fine-tuned activity & potency for each arm to simultaneously block PD-1/CTLA-4 mediated immune-suppression and VEGF mediated tumor angiogenesis.
Methods: GB268 is a hexavalent antibody with symmetrical structure, composed of anti-PD-1 VHH antibody, anti-CTLA-4 VHH antibody, and anti-VEGF conventional antibody. The Fc part is silenced by introducing L234A/L235A mutations. Comprehensive in vitro and in vivo characterization of GB268 have been carried out. Along with in vivo efficacy studies, toxicity has also been evaluated with a murine arthritis model in hPD1/hCTLA4 double-KI mice to assess immune related AEs.
Results: GB268 specifically bound to PD-1, VEGF, and CTLA-4 with high affinity and completely blocked PD-1 and VEGF pathways in reporter systems. To reduce the CTLA4 inhibition-induced AEs, the CTLA-4 arm was intentionally designed to only partially block the interaction of CTLA4 to its ligands CD80/CD86, and furthermore, the blockade of CTLA-4 was highly dependent on PD-1 expression. GB268 displayed robust anti-tumor efficacy with attenuated toxicity in murine models. In multiple PBMC-humanized models including A375 melanoma model, HT29 colorectal cancer model, and NCI-H460 NSCLC model, etc., GB268 exhibited significantly better anti-tumor efficacy, compared to PD-1/CTLA-4 bsAb and PD-1/VEGF bsAb, or in the combination of monoclonal antibodies to PD-1, CTLA-4 or VEGF. In arthritis induction model using hPD1/hCTLA4 double KI mice, GB268 had improved tolerance than cadonilimab and at least 20-fold better safety profile than ipilimumab combined with nivolumab.
Conclusions: GB268 is a first-in-class anti-PD-1/CTLA-4/VEGF tri-specific antibody with innovative design. Preclinical data demonstrated GB268 is very effective in provoking anti-tumor responses. At the meantime, immune-related AEs is alleviated. Thus, GB268 may emerge as a promising novel therapeutics for cancer treatment.

Topic of "Late-Breaking Research: Immunology 2", Number: LBPO.IM02

Title: "GBD218 — A tri-specific T cell engager (TCE) targeting BCMA and GPRC5D for treatment of multiple myeloma"

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Session LBPO.IM02 - Late-Breaking Research: Immunology 2

LB128 / 16 - A novel tri-specific T cell engager targeting BCMA and GPRC5D for treatment of multiple myeloma

April 8, 2024, 9:00 AM - 12:30 PM | Section 52

Authors

Y. Tan, X. Li, F. Yu, J. Xu, Z. Qian, Y. Cao, X. Yang, Q. Du, F. Peng, **S. Han**, Q. Ding;
Genor Biopharma Co. Ltd., Shanghai, China

Disclosures

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F. Yu, None..
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Z. Qian, None..
Y. Cao, None..
X. Yang, None..
Q. Du, None..
F. Peng, None..
S. Han, None..
Q. Ding, None.

Abstract

Introduction

Multiple myeloma (MM) accounts for 10% of all hematologic cancers. Recent advances in MM therapy have greatly increased the overall response and survival rate. However, almost all patients eventually relapse. The prognosis still remains poor. BCMA and GPRC5D are overexpressed in myeloma cells. Although CAR-T and T cell engager (TCE) targeting BCMA or GPRC5D have been efficacious in MM patients, resistance does occur. Since the expression of BCMA and GPRC5D in MM are heterogeneous, to further improve the overall response and survival, we have recently generated a novel tri-specific T-cell engager, GBD218, targeting both BCMA and GPRC5D. GBD218 has demonstrated potent ***in vitro*** and ***in vivo*** activity against myeloma cells.

Methods

Anti-BCMA and GPRC5D nanobodies were screened from alpaca immune libraries, and anti-CD3 antibody was engineered from mouse hybridoma clone. The tri-specific antibodies were constructed in a "1+1+1" format through "knob into hole" technology fused with silenced IgG1 Fc. The format of the tri-specific antibodies was optimized by multiple rounds of ***in vitro*** activity and druggability evaluation. The ***in vivo*** tumor growth inhibition effects were evaluated in PBMC-humanized xenograft mouse models.

Results

GBD218 has been designed to potently bind hBCMA (KD=0.4nM) and hGPRC5D (cell binding EC50 ~ 2nM). To reduce CRS and other potential AEs associated with TCEs, a low affinity of anti-CD3 Fab was used. In cell-based functional assays, GBD218 showed efficient cytotoxicity against single and double positive MM cell lines with various expression levels of BCMA and GPRC5D. T cell activation and cytokine release induced by GBD218, in the presence or absence of MM cancer cells, is nicely balanced for great killing efficacy and the low risk of CRS. Importantly, the results showed that GBD218 exhibited superior ***in vitro*** killing activity compared to benchmarks, including teclistamab, talquetamab, the combination of teclistamab and talquetamab, suggesting a synergistic effect of GBD218 by targeting BCMA and GPRC5D. In xenograft models, GBD218 showed excellent anti-tumor activity, indicating great potential for GBD218 as a promising therapeutics for MM.

Conclusion

GBD218 is a novel tri-specific antibody that showed potent ***in vitro*** and ***in vivo*** anti-tumor activity. GBD218 efficiently kills both BCMA and/or GPRC5D expressing MM cells, which may hold promise to increase response rate and improve survival in MM patients in clinic.

Accelerating the Clinical Pipeline Products with Critical Treatment Needs

During the Reporting Period, the Group maintained its strategy of focusing resources on its strategic priorities and, on the premise of ensuring the quality of clinical research with professionalism, making every effort to accelerate project development to provide effective treatment options to address unmet medical needs for patients in China and globally.

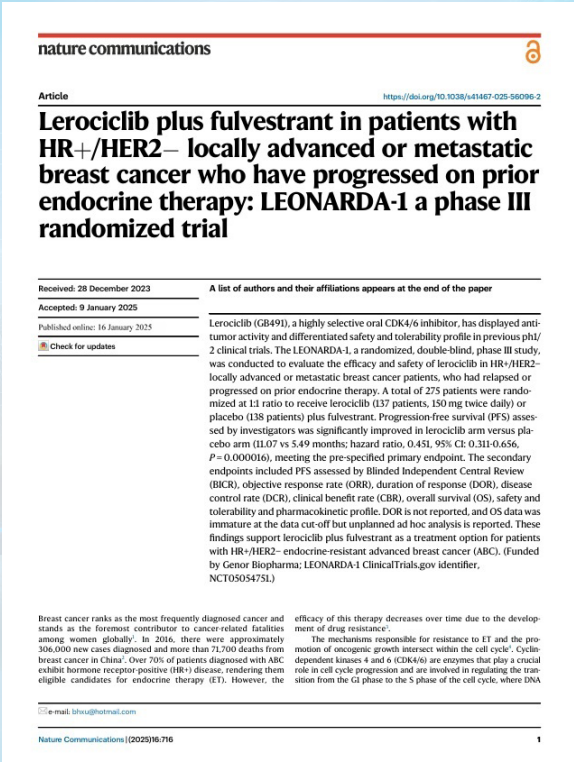
On 28 March 2023, the NMPA officially accepted the NDA of GB491 in combination with Fulvestrant for the treatment of HR+/HER2- locally advanced or metastatic breast cancer patients (second-line treatment for advanced breast cancer) with disease progression following previous endocrine therapy. On 31 August 2023, clinical on-site inspection was completed. The feedback of the NDA queries was submitted in March 2024 and the drug testing at the NIFDC was completed in May 2024. In September and October 2024, the overseas on-site production Pre-Approval Inspections of the API and the drug product plants were completed, respectively, and the reports for follow-up items of CFDI inspection were submitted to CFDI in December 2024.

The Group has also completed its patient enrolment for the phase III clinical study of GB491 in combination with letrozole as the first-line treatment for the advanced breast cancer and its interim analysis has reached the primary endpoint. We submitted the NDA to NMPA for GB491 (Lerociclib) in combination with letrozole for the treatment of locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2-negative ("HR+/HER2-") breast cancer (first-line treatment for advanced breast cancer) that had not received prior systemic antitumor therapy on 28 February 2024. The application was officially accepted on 13 March 2024. The on-site clinical inspection was completed in September 2024. The feedback on NDA queries was submitted in December 2024.

The IDMC has reviewed the efficacy and safety data from the interim analysis of the phase III clinical trial of Lerociclib in combination with letrozole as the first-line treatment for the advanced first-line breast cancer. The IDMC recommended that this clinical trial had met the prespecified requirement of statistical significance in efficacy of the interim analysis with good safety and tolerance.

The results of the interim analysis of the phase III clinical trial of GB491 in combination with letrozole as the first-line treatment for the advanced first-line breast cancer were presented in the poster discussion session at the ASCO annual meeting held in June 2024.

On 6 January 2025, the Nature Communications published the research results of GB491, Genor's highly selective oral CDK4/6 inhibitors was again recognized by authorities.



nature communications

Article

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Lerociclib plus fulvestrant in patients with HR+/HER2− locally advanced or metastatic breast cancer who have progressed on prior endocrine therapy: LEONARDA-1 a phase III randomized trial

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Check for updates

A list of authors and their affiliations appears at the end of the paper

Lerociclib (GB491), a highly selective oral CDK4/6 inhibitor, has displayed anti-tumor activity and differentiated safety and tolerability profile in previous ph1/2 clinical trials. The LEONARDA-1, a randomized, double-blind, phase III study, was conducted to evaluate the efficacy and safety of lerociclib in HR+/HER2− locally advanced or metastatic breast cancer patients, who had relapsed or progressed on prior endocrine therapy. A total of 275 patients were randomized at 1:1 ratio to receive lerociclib (137 patients, 150 mg twice daily) or placebo (138 patients) plus fulvestrant. Progression-free survival (PFS) assessed by investigators was significantly improved in lerociclib arm versus placebo arm (11.07 vs 5.49 months; hazard ratio, 0.451, 95% CI: 0.311-0.656, $P = 0.000016$), meeting the pre-specified primary endpoint. The secondary endpoints included PFS assessed by Blinded Independent Central Review (BICR), objective response rate (ORR), duration of response (DOR), disease control rate (DCR), clinical benefit rate (CBR), overall survival (OS), safety and tolerability and pharmacokinetic profile. DOR is not reported, and OS data was immature at the data cut-off but unplanned ad hoc analysis is reported. These findings support lerociclib plus fulvestrant as a treatment option for patients with HR+/HER2− endocrine-resistant advanced breast cancer (ABC). (Funded by Genor Biopharma; LEONARDA-1 ClinicalTrials.gov identifier, NCT05054751.)

Breast cancer ranks as the most frequently diagnosed cancer and stands as the foremost contributor to cancer-related fatalities among women globally[1]. In 2016, there were approximately 306,000 new cases diagnosed and more than 71,700 deaths from breast cancer in China[2]. Over 70% of patients diagnosed with ABC exhibit hormone receptor-positive (HR+) disease, rendering them eligible candidates for endocrine therapy (ET). However, the efficacy of this therapy decreases over time due to the development of drug resistance[3].

The mechanisms responsible for resistance to ET and the promotion of oncogenic growth intersect within the cell cycle[4]. Cyclin-dependent kinases 4 and 6 (CDK4/6) are enzymes that play a crucial role in cell cycle progression and are involved in regulating the transition from the G1 phase to the S phase of the cell cycle, where DNA

e-mail: bhxu@hotmail.com

The clinical study data of the world's first EGFR/cMET/cMET tri-specific antibody (GB263T) under Genor was presented at international industry conferences, gaining global recognition while demonstrating the highly differentiated advantages and efficient clinical advancement of the company's self-developed products.

The updated research data of GB263T (EGFR/cMET/cMET, TsAb) have been accepted by the ESMO Congress 2024 and were published on 14 September 2024.As of 31 December 2023, a total of 15 patients had received at least one GB263T (EGFR/cMET/cMET, TsAb) treatment. All patients had received previous third-generation EGFR-TKI and platinum-based chemotherapy and the median number of prior lines of systemic therapy was 3.

During the year, Genor focused on accelerating clinical pipeline products as its business development priority. We have been actively pursuing the possibility of realizing the potential of pipeline results in the international market, to promote the process of bringing innovative drugs to the market to address the unmet needs of patients. Given the promising efficacy and good safety profile of GB261 (CD20/CD3, BsAb), the Group successfully entered into the License Agreement and the Stock Purchase Agreement with TRC 2004 to explore its potential in autoimmune diseases. This new model of empowerment and participation in development is another milestone in Genor's innovation.

Continuously Strengthening the IP Management System

The Group strictly complies with applicable laws and regulations, such as the Patent Law, the Trademark Law and the Copyright Law of the PRC. The Group has employed policies of Confidentiality and IP Management, Invention Submission and Patent Evaluation, Report and Paper Publication, the Trademark Management Code and the Trademark Use Code. Following the principle of "creation, application and protection", we have established and continuously strengthened our own IP management system, to support the Group's key product pipeline development. We arrange routine internal trainings for enhancing professional competency of relevant staff member.

During the Reporting Period, we closely followed the standard update of Enterprise intellectual property compliance management system — Requirements GB/T29490-2023 (a replacement of Enterprise intellectual property management GB/T29490-2013), and have actively taken initiatives, including internal briefings and refinement of detailed requirements in terms of management system, application submission and relevant contractual terms in accordance with the new standard. As a result, the Group successfully renewed the Certification of National Intellectual Property Compliance Management System in November 2024.


知识产权合规管理体系认证证书

兹证明

嘉和生物药业有限公司

知识产权合规管理体系符合标准： GB/T 29490-2023

通过认证范围：

中规认证

中规（北京）认证有限公司

In August 2024, we organized a professional training on the application of incoPat, a global patent search and analysis system, to help the staff in relevant departments to better understand and leverage professional databases for patent search and applications more effectively; and a total of 24 employees participated in the one-hour training.

During the Reporting Period, the Group completed 4 invention patent applications and received 2 approvals, leading to a total number of invention patent applications to 89 and valid patents of 45. To support the Group's momentum of innovative products' going global, we strengthened cross-team collaboration and submitted 4 Patent Cooperation Treaty ("PCT") applications for key R&D pipelines, and another PCT application to multiple countries and regions.

04

Continuously Optimizing Quality Management

- Quality Control of Clinical Research
- Patient Safety and Information Protection
- Quality Assurance of Outsourced Production
- Supply Chain Management

While developing innovative drugs, Genor adheres to the ethical guidelines for human medical research set out in the Declaration of Helsinki (the World Medical Association, WMA), strictly complies with the relevant laws and regulations in all aspects of its business to provide safe and effective investigational drugs for investigators and patients, including China's Drug Administration Law, the Measures for the Administration of Drug Registration, the Good Manufacturing Practices, the Measures for the Supervision and Administration of Drug Production, and the Measures for the Reporting and Monitoring of Adverse Drug Reactions. The Group is committed to ensuring that clinical studies fully satisfy the requirements of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ('ICH'), and Good Practice ('GxP') quality guidelines.

Genor has always put drug quality and patient safety first, and has been making continuous improvement to its quality management system to fulfil its product responsibility with foresight and agility in order to respond to changes in external environmental and serve its own strategic development.

Quality Control of Clinical Research

The Group's clinical research follows the Measures for the Quality Management of Pharmaceutical Clinical Trials, which covers the whole aspects and phases of clinical trials, in the areas of clinical operations, medical surveillance, data management and pharmacovigilance. We develop our clinical trial study plan with uncompromising principle of safeguarding patient safety and wellbeing, and execute clinical programs through a collaboration model with qualified contract research organizations ('CRO') following the designed trial protocols.

We adopt a compatible model that integrates our own standard operating procedures ("SOPs") with SOPs of partner CROs, based on which we formulate project management plans that encompass activities such as monitoring, data validation, risk management, data analysis and synthesis. We perform regular audits on the CROs' quality management, technical assurance and training systems. We do not own or have direct access to personal data of the subjects while performing our duty monitoring CROs' operational compliance and data accuracy and validity, and we emphasize the area of privacy protection and informed consent process for the subjects.

Genor's internal clinical trial management policies include:

- *Technical Guidelines for Electronic Data Collection in Pharmaceutical Clinical Trials*
- *Technical Guidelines for Clinical Trial Data Management*
- *Measures for Quality Management of Pharmaceutical Clinical Trials*
- *Requirements for Drug Records and Data Management (Pilot version)*
- *Guidelines for Essential Document Retention for Pharmaceutical Clinical Trials*

Quality Management of Clinical Trials

- Routine Quality Control, including regular data review, data quality monitoring, and error identification and correction
- On site QC visits and Quality Assurance inspections, to perform routine risk audits
- Supplier Quality Management, through robust supplier management to assure the quality of clinical research projects

Implementation of Quality Requirements in Project Workflow Design

Clinical Trail Operation	Data Management	Pharmacovigilance	Medical Surveillance	Others
clinical research center selection and setting-up, drug management, biosample management, resource supply management, basic documentation, informed consent, research center closure	Case Report Form ('CRF') design and database establishment, data management plan, data cleaning, database locking, etc.	Reporting of serious adverse events, Drug Safety Update Reports ('DSUR') preparation during the study period	Discussion of subject enrolment eligibility, management of protocol violations, medical surveillance process.	Statistical analysis, medical report writing, etc.

In addition to daily management and monitoring, we ensure comprehensive training plans are in place for each project team and relevant personnel are fully briefed to undertake their tasks and ensure the quality of project implementation.

During the Reporting Period, we conducted approximately 70 quality assurance visits for GB491–008 project alone, including 7-inspections of key research centers. These relentless efforts helped us ensure the robustness of our quality management and compliance adherence.

Patient Safety and Information Protection

In line with regulatory requirements and industry regulations, 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, Genor is committed to delivering high-standard practices in data and privacy protection and pharmacovigilance, jointly performed with investigators, hospitals and CROs, whereby subjects' rights to information and consent are duly safeguarded. At the same time, the Group has been building its adverse event ("AE") reporting management capacity required for approved drugs in line with the progress of its pipeline.

During the Reporting Period, the Group updated and implemented internal measures, such as 'Product Complaint Management' and 'Drug Recall Management', in accordance with below regulatory updates issued by the Center for Drug Evaluation under NMPA:

- *Notice of Public Consultation on the Draft Guidelines on ICHE2D (R1) "Post-marketing Safety Data: Definitions and Standards for the Management and Reporting of Individual Safety Reports"*
- *Notice on 'the Draft Guidelines on Post-marketing Safety Risk Communication for Pharmaceuticals (Draft for Comment)'*
- *Notice of Technical Guidelines for SUSAR Analysis and Processing in Clinical Trials of Antineoplastic Drugs (No. 42 of 2024)*

Genor has a Drug Safety Committee, which undertakes its responsibility in areas of deliberation on major risk, handling of major or emergency drug safety events, decisions on risk controls and pharmacovigilance-related matters in accordance with the Group's Drug Safety Committee Charter. During the Reporting Period, the Drug Safety Committee reviewed the summary analyses of AE reports on a regular basis and made enquiries and proposed mitigation measures to identified risks.

AE Management

Governance

Drug Safety Committee

Process

Quality verification, medical assessment, training review and service provider audit, and AE reporting.

Execution

Project team consisting of in-house team and CRO partners regularly check the quality of clinical pharmacovigilance reports and submission compliance and channel effectiveness.

Database

Completed the interface with the Center for Drug Evaluation, NMPA and Centre for Drug Reevaluation, NMPA, realizing electronic submission that ensures the compliance of the submission limit.

Improvement

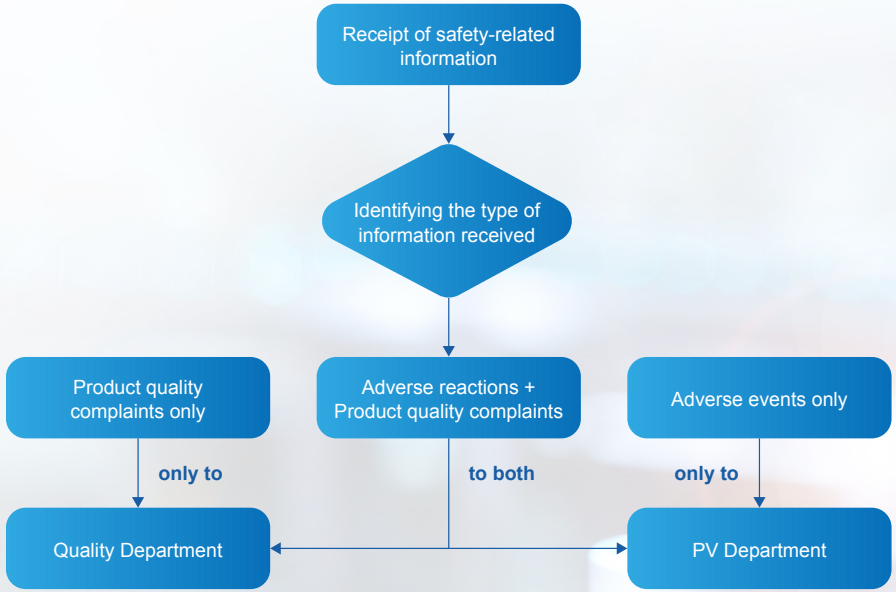
Enhanced risk warning and related training during project implementation, strengthening in-house team's capability and responsibility of report conduction and optimize relevant internal communications.

Outputs

Completed quality checks, medical evaluations and simultaneous distribution to relevant regulatory bodies and research centers smoothly and in accordance with relevant regulatory guidelines.

Genor requires all employees to be informed of the AE reporting protocols and to report identified cases within 24 hours after receiving the relevant information. In 2024, we conducted routine training on AE reporting for staff, which covered areas in responsibilities, definition of drug safety information, reporting sources, reporting requirements and channels, and regulatory requirements, etc., with particular emphasis on the serious consequences of failing to submit reports in accordance with the requirements.

During the Reporting Period, Genor was compliant with the reporting timeline requirement for all adverse reactions and serious adverse events. We did not receive any AE report relating to our previously approved products[2].



Quality Assurance of Outsourced Production

In recent years, the Group's strategy and resource investment has been focusing on the research and development of innovative medicines. From the end of 2023, all investigational drugs used in clinical research projects have been developed and manufactured by CDMOs. Genor undertakes its responsibilities in the capacities of a principal and Marketing Authorization Holder ('MAH'), establishing a framework agreement with the CDMOs, under which supervises and audits their development methodology, raw material testing, process development, and process control, release testing and GMP compliance, as well as corrective measures and actions, in accordance with the relevant national regulations and requirements. Both parties agreed on product quality standards, including raw material quality, process control and product testing standards, and have maintained regular communication at least once every two weeks. Genor releases batches of final products in accordance with GMP standards, with product labelling controls to satisfying the requirements on clarity and accuracy in terms of intended use, indication for use, and instructions. We continuously monitor the efficacy, safety and continuity of product supply, with improved efficiency with our CDMOs.

During the Reporting Period, we also invested resources in building MAH competency for approved medicine in light of the application process of the GB491 project, and carried out solid work in the areas of CDMO pre-qualification and improvement, risk assessment and management, and capability of the quality team.

[2] There was no approved drug product being marketed by Genor in 2024.

All-out Efforts for the Commercialization of GB491

MAH system construction and document revision: 80+ system construction documents and management specifications were updated in accordance with GMP requirements, to fully meet the compliance requirements of GB491 entering the commercialization phase.

- Organization Chart and Functional Responsibility Management
- Health management for CDMO on-site supervisory personnel
- Quality policy, quality target management and management processes
- Product shipment management, enabling supply chain traceability after product release

Team capacity: Strengthening of the quality team through additional personnel and capacity building in the context of the Group's optimization and focus strategy.

- Train all staff on quality system documentation and equip them to support international and domestic on-site and remote inspections
- Complete self-inspections and a mock product recall for gap analysis
- Utilize external learning platforms to keep regulatory knowledge up to date and participate in hands-on training

CDMO pre-inspection and improvement: Conducted multiple pre-audits prior to formal Pre-Approval Inspection ('PAI'), identified potential defects and implemented corrective actions to ensure successful passage of PAI.

- Conducted on-site audits for all 9 CDMOs at home and abroad, and provided on-site/remote review and technical guidance for 15 major defects and more than 50 minor defects identified; the rectification plans have all been completed
- Provided on-site training to overseas CDMOs on the differences between the requirements for commercial drug manufacturing in China and overseas markets

Risk assessment and management: Risk assessment of the production design of GB491 to ensure stability of supply, reliability of quality and value for money of the drug after its introduction to the market

- Adequately assess and prepare for geopolitical and other external risk factors
- Since the manufacturing design stage, the transport and storage conditions have been fully considered to ensure safety of patients, while focusing on reducing packaging and improving the efficiency of resource use

Supply Chain 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. We continue to require formal pledge and encourage active practice from suppliers to counter corruptions in line with our internal policy, namely the Special Provisions on Anti-bribery and Anti-corruption.

Genor emphasizes service and production quality and delivery capability in its procurement activities, assessing the potential to deliver value-added and after-sales service, as well as reviewing relevant track records. Our service providers typically include CROs, CDMOs, logistic providers, testing and validation services, and audit agencies. All collaborations are grounded on a satisfactory outcome from our evaluation on quality standards, compliance performance, data and system reliability. We conducted an in-depth assessment of the above performance in three stages, namely supplier introduction, service quality review and regular audits. A supplier annual audit plan, with both onsite and external third-party audits, is developed to proactively monitor and mitigate risks.

Genor has continuously enhance the outsourced production model and further strengthened the requirements and supervision of key CDMO material suppliers. During the Reporting Period, we carried out risk and potential assessments in areas of financial stability, technological advantages, execution capabilities, quality systems and management processes, and business reputation, and screened suitable suppliers based on quantitative indicators.

As of the end of 2024, the Group had a total of 51[3] active suppliers (inclusive of 4 new suppliers), among them 37 are service providers supporting clinical research programs.

Shanghai, China	Other locations, China	Overseas
12	23	16

[3] The total number of suppliers included all suppliers available in the Company's system per previous reports.

05

Employee Interests and Hiring Practice

Each employee's wisdom and dedicated effort has contributed to Genor's innovation and development. We highly respect and value our employees by fulfilling our employer responsibilities and obligations and committing to building the corporate value encompassing Company overall interest, Entrepreneurship, Trust-building, Mutual respect and Challenge-taking. The Group creates an 'open, inclusive and encouraging pursuit of excellence' working culture to support employees to continuously consolidate their professional competences and general qualities to realize their own value.

During the Reporting Period, Genor has persisted in its strategy of *Focusing, Optimizing, Accelerating and Expanding*. We actively explored and adjusted business development and operational plans with agility to cope with the increasingly complex economic environment and challenges of the biopharmaceutical sector, so as to ensure the orderly progress of our core pipeline and business priorities, promoting the achievement of the Company's medium-to long-term development goals.

- Strategic Adjustment and Internal Communication
- Fair Employment and Interests Protection
- Learning Culture and Professional Development
- Occupational Safety and Health
- Community Building

Strategic Adjustment and Internal Communication

Vital strategic adjustments come with organizational change adaptively. To address external and internal challenges, during the Reporting Period, the Group fully focused strategic resources on clinical and pipeline development projects that can rapidly deliver innovative treatment options to patients, and continued adopting a more flexible collaboration model, resolutely promoting results of pipeline products and business collaborations.

Based on the above considerations, and with due regard to our responsibilities and obligations to investors, healthcare professionals, partners, patients and employees, the Group further consolidated the structure and size of its staff team during the year to support the implementation of the Company's transformation, while ensuring the advancement of the pipeline and the high-quality delivery of outsourced production. It also ensured to retain vital forces and expansion potential in terms of human resource for the merge with Edding.

Genor sincerely appreciates the hard work of every employee. In the process of the organization restructure, we established a coordination mechanism led by the human resources department, supported by the legal team and senior management's direct engagement, and have actively conducted internal communication in an open, transparent and responsible manner. For each affected employee, we provided reasonable compensation package under the premise of legal compliance and necessary transition assistance, to maintain healthy labor relations. In addition, the Group has mandated several departing employees to provide consulting services at they can continue to support the efficient and smooth handover and ongoing daily operation with mutual benefits.

Genor also pays attention to the concerns and expectations of existing employees about the Group's prospects given the organizational changes. We encourage all employees to frankly express their views through online meetings or face-to-face dialogues, keep upward communication channels open and require managers, human resources department and senior management to response timely and provide sufficient feedback.

Fair Employment and Interests Protection

Genor 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, Labor Contracts, and Probation Periods to standardize its human resource related practices, in terms of pay and termination, working hours and other entitlements and benefits.

Genor fulfills its employer responsibilities by applying a people-oriented approach. Our hiring practices follow the principles of fairness and impartiality and takes a merit-based and freewill 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 labor or child labor 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.

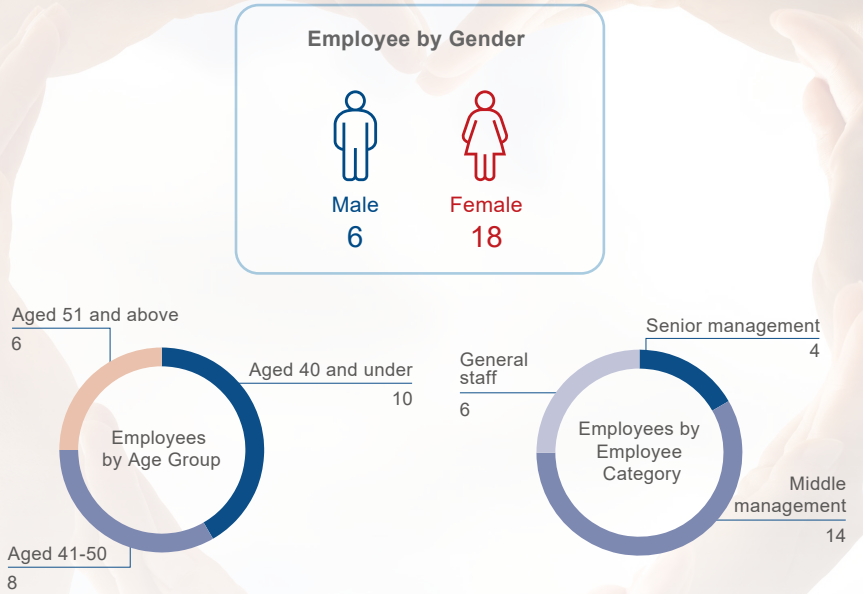
The Group provides employees with competitive compensation and welfare packages. Our remuneration primarily encompasses basic salary, various bonuses and allowances, with a portion of variables based on performance and the employee stock option plan in place. We conducted annual performance appraisal for all employees, and related results were applied as critical inputs for the calculation of annual performance bonuses, salary increments, promotions, and career development.

All Genor employees are eligible for leaves such as paid holidays, statutory holidays, annual leave, marriage leave, compassionate leave, maternity leave, and paternity leave. 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.

During the Reporting Period, for the well-being of employees, Genor continued to adopt flexible working policy company-wide, allowing employees to work remotely as long as team efficiency and work quality is ensured and support their building of work-life balance.

As of 31 December 2024, Genor had a total of 24 full-time employees and 9 part-time employees. All full-time employees were located in Mainland China, 70.8% of which served research-related positions, and 50% of employees held master ’s degree or beyond.

Information on Full-time Employee Distribution by Gender, Age Group, and Employee Category[4]

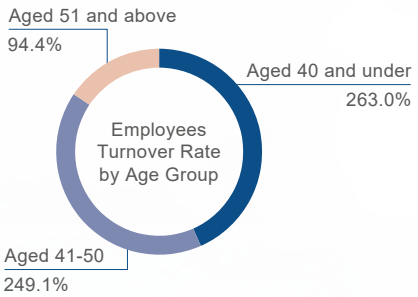


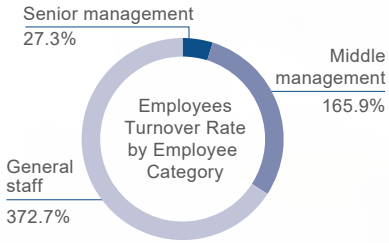
[4] Employee category distribution and turnover rates are calculated and disclosed based on the number of full-time employees only.

In 2024, the Group's overall employee turnover rate was 226.2%. Employee turnover rates by category were as follows:

Employee Turnover Rate by Gender

Male	Female
220.2%	228.1%





Learning Culture and Professional Development

Despite organizational changes, the Group continues to encourage and maintain a lifelong learning culture and professionalism in the workplace, supports and promotes personalized career paths and choices, and helps employees to pursue their own growth and sense of value.

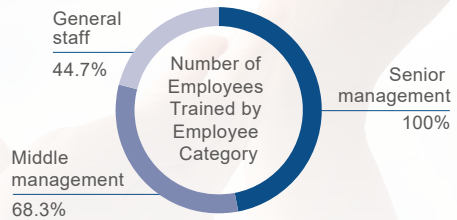
During the Reporting Period, the Group provided certain professional positions such as pharmacovigilance, legal affairs and compliance with internal and external training opportunities delivered by regulators and external experts, to ensure compliant operations and effective risk prevention and control of core business processes, as well as the maintenance of the team's expertise and capabilities. In addition, all serving employees have completed the trainings on Business Ethics for Listed Companies and Adverse Event Reporting in 2024, with a 100% pass rate on the tests attached to those trainings.

During the Reporting Period, Genor recorded a total of 138 training hours, with an average training hours per employee stood at 3.67 hours.

Information on Staff Training

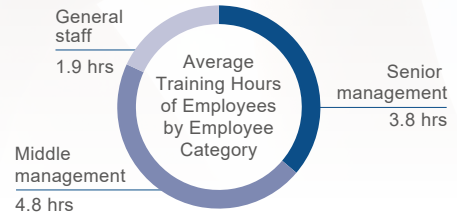
Percentage of Employees Trained by Gender

Male	Female
66.1%	63.2%



Average Training Hours of Employees by Gender

Male	Female
4.8 hrs	3.3 hrs



Occupational Safety and Health

Genor adheres strictly to relevant laws and regulations, such as the Work Safety Law of the People's Republic of China, the Emergency Response Law of the People's Republic of China, has developed and implemented internal system for workplace safety, safeguarding the occupational health and safety of our employees and those within locations where Group operates.

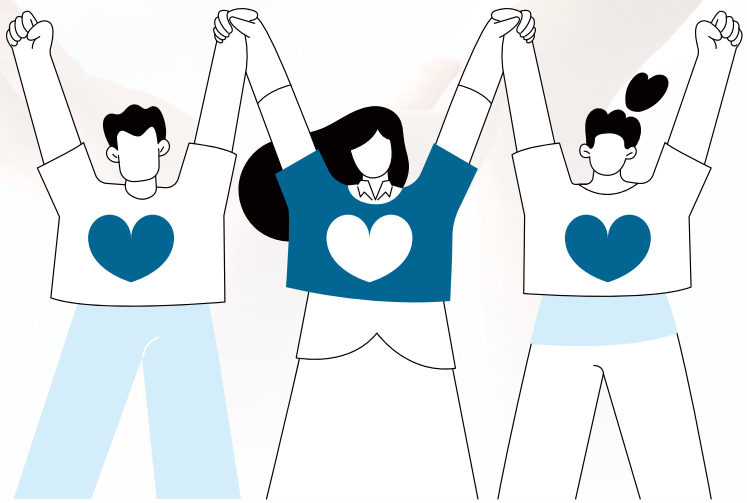
To raise awareness, occupational health is included into the onboarding training for new employees and annual refreshing safety training for all full-time employees.

The Group closed its early research lab in Shanghai at the beginning of the year. In terms of safety management prior to its closure, the Group ensured compliance management, employed internal policies including the Operating Procedures for Laboratory Safety Management, the Operating Procedures for Occupational Health Management, the Operating Procedures for Emergency Responses to Safety Incidents/Accidents and the Emergency Response Plan for Production Safety Accidents, and strictly complied with internal procedures, including the Operating Procedures for the Management of Hazardous Chemicals, the Operating Procedures for the Management of Highly Toxic Chemicals, the Operating Procedures for the Management of Precursor Chemicals, 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. During the implementation of the Shanghai lab's closure, we handled the preservation and disposal of all hazardous chemicals and waste in accordance with the above protocols and policies.

During the Reporting Period and two prior years, the Group had recorded no material safety accidents or fatalities, and the number of days lost due to work-related injuries for 2024 was nil.

Community Building

We had to temporarily suspend our participation in volunteer services for local communities and charities due to the undergoing of our organizational transformation during 2024.



06

Climate and Environment

Climate change and more frequent natural crisis events pose greater risks and burdens to human health and global public health system. While focusing on patient-centered R&D and innovation, Genor leverages its capabilities and strengths in CMC to actively optimize the efficiency of resource and energy utilization during the R&D and manufacturing processes, and to reduce the presence of pharmaceuticals in the environment. At the same time, we continually evaluate and manage the energy consumption in our owned offices, to minimize the environmental footprint of our day-to-day operations and to fulfil our environmental responsibility[5].

- Energy Consumption and Carbon Emission Control
- Resource Usage

[5] During the Reporting Period, as a result of business restructuring, the Group's operations no longer included owned medicine production and early-stage research, and therefore no longer generated exhaust gas emission, wastewater discharge, or hazardous waste.

Energy Consumption and Carbon Emission Control

During the Reporting Period, Genor's business involved in early discovery, clinical research and outsourced production of drugs for clinical use. In view of the further consolidation of the Group's strategic focus, we closed our early discovery laboratory in Shanghai and the Beijing office in early 2024. In the Reporting Period, Genor's operations were carried out all in rented offices, thus its GHG emissions mainly came from purchased electricity (Scope 2) and related value chain activities (Scope 3).

We adopted energy-efficient equipment and environmentally friendly design in the office and promoted a green and paperless office. In addition, we have reduced energy and resource consumption by implementing a Group-wide flexible working policy that promotes online meetings and reduces staff commuting emissions.

As part of our regular operations, we maintain monitoring and assessment of energy consumption, environmental risks and resource efficiency in our office. In the Reporting Period, we have put on hold the environmental targets published in 2021 due to the ongoing strategic adjustments and proposed mergers that are expected to introduce changes including redefinition of the environmental impacts and energy consumption structure of the Group.

Greenhouse Emissions	Unit	2024	2023	2022
Direct GHG Emissions (Scope 1)	tCO_2e	**16.36**	19.82	17.95
Indirect GHG Emissions (Scope 2)	tCO_2e	**13.11**	2,467.34	6,173.53
Total GHG Emission (Scope 1&2)	tCO_2e	**29.47**	2,487.16	6,191.48
Total GHG Emission Intensity	tCO_2e/Average Number of Employees	**0.78**	13.41	14.47

Type of Energy	Unit	2024	2023	2022
Diesel	MWh	**N/A**	N/A	2.62
Gasoline	MWh	**59.60**	72.23	65.39
Purchased Electricity	MWh	**22.42**	4,254	10,644
Purchased Steam	MWh	**N/A**	743	2,351
Total Energy Consumption	MWh	**82.02**	5,069	13,063
Total Energy Consumption Intensity	MWh/Average Number of Employees	**2.18**	27.33	30.52

Resource Usage

During the Reporting Period, the Group's resource consumption was mainly for daily office supplies, and the total consumption of all types of resources was significantly lower than in previous years. Our water consumption was sourced from the municipal water supply at our main operating sites; the waste generated was non-hazardous office waste. As we provide clinical drugs through outsourced manufacturing, there was no owned production and use of packaging. Hazardous waste such as trace amounts of waste liquids, end-of-life reagents and waste reagent glass bottles generated prior to the closure of our Shanghai early research laboratory, were disposed of appropriately in accordance with the relevant regulations at the time of closure.

Water Resource Management	Unit	2024	2023	2022
Total Water Consumption	Tonne	**13.43**	24,007	93,100
Total Water Consumption Intensity	Tonne/Average Number of Employees	**0.36**	129.42	217.52

APPENDIX

HKEX ESG Reporting Guide Content Index

Subject Areas, Aspects, Disclosures and KPIs	Description	Sections
Aspect A1: Emissions		
General Disclosure	Information on: (a) the policies; and (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.	Part 6 Climate and Environment
KPI A1.1	The types of emissions and respective emissions data.	Part 6 > Energy Consumption and Carbon Emission Control
KPI A1.3	Total hazardous waste produced (in tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility).	Not applicable
KPI A1.4	Total non-hazardous waste produced (in tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility).	Part 6 > Resource Usage
KPI A1.5	Description of emission target(s) set and steps taken to achieve them.	Part 6 > Energy Consumption and Carbon Emission Control
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 6 > Energy Consumption and Carbon Emission Control
Aspect A2: Use of Resources		
General Disclosure	Policies on the efficient use of resources, including energy, water and other raw materials.	Part 6 > Resource Usage
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 6 > Energy Consumption and Carbon Emission Control
KPI A2.2	Water consumption in total and intensity (e.g., per unit of production volume, per facility).	Part 6 > Resource Usage
KPI A2.3	Description of energy use efficiency target(s) and steps taken to achieve them.	Part 6 > Energy Consumption and Carbon Emission Control
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 6 > Resource Usage
KPI A2.5	Total packaging material used for finished products (in tonnes) and, if applicable, with reference to per unit produced.	Not applicable

Subject Areas, Aspects, Disclosures and KPIs	Description	Sections
	Aspect A3: The Environment and Natural Resources	
General Disclosure	Policies on minimising the issuer's significant impact on the environment and natural resources.	Part 6 Climate and Environment
KPI A3.1	Description of the significant impacts of activities on the environment and natural resources and the actions taken to manage them.	Part 6 Climate and Environment
	Aspect B1: Employment	
General Disclosure	Information on: (a) the policies; and (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.	Part 5 > Strategic Adjustment and Internal Communication; Fair Employment and Interests Protection
KPI B1.1	Total workforce by gender, employment type (e.g. full-or part-time), age group and geographical region.	Part 5 > Fair Employment and Interests Protection
KPI B1.2	Employee turnover rate by gender, age group and geographical region.	Part 5 > Fair Employment and Interests Protection
	Aspect B2:Health and Safety	
General Disclosure	Information on: (a) the policies; and (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.	Part 5 > Occupational Safety and Health
KPI B2.1	Number and rate of work-related fatalities occurred in each of the past three years, including the reporting year.	Part 5 > Occupational Safety and Health
KPI B2.2	Lost days due to work injury.	Part 5 > Occupational Safety and Health
KPI B2.3	Description of occupational health and safety measures adopted, and how they are implemented and monitored.	Part 5 > Occupational Safety and Health
	Aspect B3:Development and Training	
General Disclosure	Policies on improving employees' knowledge and skills for discharging duties at work. Description of training activities.	Part 5 > Learning Culture and Professional Development
KPI B3.1	The percentage of employees trained by gender and employee category (e.g., senior management, middle management).	Part 5 > Learning Culture and Professional Development
KPI B3.2	The average training hours completed per employee by gender and employee category.	Part 5 > Learning Culture and Professional Development

Subject Areas, Aspects, Disclosures and KPIs	Description	Sections
Aspect B4: Labour Standards		
General Disclosure	Information on: (a) the policies; and (b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to preventing child and forced labour.	Part 5 > Fair Employment and Interests Protection
KPI B4.1	Description of measures to review employment practices to avoid child and forced labour.	Part 5 > Fair Employment and Interests Protection
KPI B4.2	Description of steps taken to eliminate such practices when discovered.	Part 5 > Fair Employment and Interests Protection
Aspect B5: Supply Chain Management		
General Disclosure	Policies on managing environmental and social risks of the supply chain.	Part 4 > Supply Chain Management
KPI B5.1	Number of suppliers by geographical region.	Part 4 > Supply Chain Management
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 > Supply Chain Management
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 > Supply Chain Management
KPI B5.4	Description of practices used to promote environmentally preferable products and services when selecting suppliers, and how they are implemented and monitored.	Not applicable
Aspect B6: Product Responsibility		
General Disclosure	Information on: (a) the policies; and (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.	Part 4 > Patient Safety and Information Protection
KPI B6.1	Percentage of total products sold or shipped subject to recalls for safety and health reasons.	Not applicable
KPI B6.2	Number of products and service-related complaints received and how they are dealt with.	Part 4 > Patient Safety and Information Protection
KPI B6.3	Description of practices relating to observing and protecting intellectual property rights.	Part 3 > Continuously Strengthening the IP Management System
KPI B6.4	Description of quality assurance process and recall procedures.	Part 4 > Patient Safety and Information Protection
KPI B6.5	Description of consumer data protection and privacy policies, and how they are implemented and monitored.	Part 4 > Quality Control of Clinical Research; Patient Safety and Information Protection

Subject Areas, Aspects, Disclosures and KPIs	Description	Sections
Aspect B7: Anti-Corruption		
General Disclosure	Information on: (a) the policies; and (b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to bribery, extortion, fraud and money laundering.	Part 2 > ESG Governance > 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 > ESG Governance > Compliance Management
KPI B7.2	Description of preventive measures and whistle-blowing procedures, how they are implemented and monitored.	Part 2 > ESG Governance > Compliance Management
KPI B7.3	Description of anti-corruption training provided to directors and staff.	Part 2 > ESG Governance > 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 5 > 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
Part D: Climate-related Disclosure		
Governance	Governance skills, approach and capabilities; role and responsibilities of the Board; monitoring process; role and responsibilities of management	Part 2 > ESG Governance
Strategy	Climate-related risks and opportunities; business model and value chain; climate resilience; strategy and decision-making	Part 2 > ESG Governance
Risk Management	Risk identification and assessment	Part 2 > Climate Risk and Opportunity
Metrics and Targets	Greenhouse gas emissions and related targets	Part 2 > Climate Risk and Opportunity