

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



**BeiGene, Ltd.**

**百濟神州有限公司**

*(incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 06160)**

## **INSIDE INFORMATION**

### **UNAUDITED RESULTS FOR THE THREE MONTHS ENDED DECEMBER 31, 2022 AND AUDITED RESULTS FOR THE YEAR ENDED DECEMBER 31, 2022 OF BEIGENE, LTD. AND BUSINESS UPDATES**

This announcement is issued pursuant to Rule 13.09 of the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and under Part XIVA of the Securities and Futures Ordinance (Cap. 571).

BeiGene, Ltd. (the “**Company**” or “**BeiGene**”) is pleased to announce its unaudited consolidated financial results for the fourth quarter ended December 31, 2022 and audited consolidated financial results for the year ended December 31, 2022 and business updates.

The Company is pleased to announce the unaudited consolidated results of the Company and its subsidiaries (the “**Group**”) for the fourth quarter ended December 31, 2022 (the “**Quarterly Results**”) and audited consolidated financial results of the Group for the year ended December 31, 2022 (the “**Annual Results**”) published in accordance with applicable rules of the U.S. Securities and Exchange Commission and recent business highlights and expected milestones for 2023 (the “**Business Updates**”).

The Quarterly Results and Annual Results have been prepared in accordance with U.S. Generally Accepted Accounting Principles (“**U.S. GAAP**”), which are different from the International Financial Reporting Standards (“**IFRSs**”).

Attached hereto as Schedule 1 is the full text of the press release issued by the Company on February 27, 2023, in relation to the Quarterly Results and Annual Results (unless otherwise provided, all dollar amounts set out below are denominated in United States dollars) and Business Updates, some of which may constitute material inside information of the Company.

The Company expects to issue its annual results for the year ended December 31, 2022 on or before March 31, 2023 in accordance with the Listing Rules, which will include a statement showing the financial effect of any material differences between the financial statements reported under U.S. GAAP and IFRS.

This announcement contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding clinical data for BeiGene’s drug candidates and approvals of its medicines; the conduct of late-stage clinical trials and expected data readouts; additional planned product approvals and launches; the advancement of and anticipated clinical development, regulatory approvals and other milestones and commercialization of BeiGene’s medicines and drug candidates; the potential for BRUKINSA to provide clinical benefit to patients with CLL compared with the comparator drug; the success of BeiGene’s commercialization efforts and revenue growth; the expected capacities and completion dates for the Company’s manufacturing facilities under construction; the impact of the COVID-19 pandemic on the Company’s clinical development, regulatory, commercial, manufacturing, and other operations; BeiGene’s plans and the expected events and milestones under the captions “Recent Business Highlights” and “Expected Milestones”; and BeiGene’s plans, commitments, aspirations and goals under the caption “About BeiGene”. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene’s ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene’s ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene’s ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene’s reliance on third parties to conduct drug development, manufacturing, commercialization and other services; BeiGene’s limited experience in obtaining regulatory approvals and commercializing pharmaceutical products; BeiGene’s ability to obtain additional funding for operations and to complete the development of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on BeiGene’s clinical development, regulatory, commercial, manufacturing and other operations, as well as those risks more fully discussed in the section entitled “Risk Factors” in BeiGene’s most recent quarterly report on Form 10-Q as well as discussions of potential risks, uncertainties, and other important factors in BeiGene’s subsequent filings with the U.S. Securities and Exchange Commission and The Stock Exchange of Hong Kong Limited. All information in this announcement is as of the date of this announcement, and BeiGene undertakes no duty to update such information unless required by law.

The Company’s shareholders and potential investors are advised not to place undue reliance on the Quarterly Results and Annual Results and to exercise caution in dealing in securities in the Company.

By order of the Board  
**BeiGene, Ltd.**  
**Mr. John V. Oyler**  
*Chairman*

Hong Kong, February 27, 2023

*As of the date of this announcement, the Board of Directors of the Company consists of Mr. John V. Oyler as Chairman and Executive Director, Dr. Xiaodong Wang and Mr. Anthony C. Hooper as Non-executive Directors, and Dr. Margaret Han Dugan, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Ranjeev Krishana, Mr. Thomas Malley, Dr. Alessandro Riva, Dr. Corazon (Corsee) D. Sanders and Mr. Qingqing Yi as Independent Non-executive Directors.*

## Schedule 1

### BeiGene Reports Fourth Quarter and Full Year 2022 Financial Results

- *Recorded product revenue of \$339.0 million and \$1.3 billion for the fourth quarter and full year, respectively, increasing 72.3% and 97.9% from the prior-year periods*
- *BRUKINSA® product revenue totaled \$176.1 million and \$564.7 million for the quarter and full year, respectively, increasing 101% and 159% from the prior-year periods*
- *Tislelizumab product revenue totaled \$102.2 million and \$422.9 million for the quarter and full year, respectively, increasing 88% and 66% from the prior-year periods*
- *BRUKINSA now approved in the U.S. to treat adult patients with relapsed/refractory (R/R) and first-line chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), and in the EU to treat CLL*
- *Presented data from final analysis of the Phase 3 ALPINE trial demonstrating progression-free survival superiority for BRUKINSA versus IMBRUVICA® in R/R CLL/SLL as a late breaking abstract at ASH 2022; simultaneously published in The New England Journal of Medicine*

BASEL, Switzerland; BEIJING; and CAMBRIDGE, Mass. — February 27, 2023 — BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today reported financial results for the fourth quarter and full year 2022, recent business highlights, and upcoming milestones.

“We had an outstanding fourth quarter and 2022, with revenues from our two cornerstone medicines, BRUKINSA® and tislelizumab, dramatically increasing as our global team continues to bring these innovative therapies to more patients and their caregivers,” said John V. Oyler, Co-Founder, Chairman and Chief Executive Officer at BeiGene. “The final progression-free survival (PFS) analysis of the ALPINE trial demonstrating superior efficacy and a favorable cardiac safety profile compared to IMBRUVICA® in relapsed/refractory (R/R) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and the recent U.S. FDA approval for BRUKINSA in adult patients with CLL/SLL were the most impactful of many recent milestones for our company and a testament to our commitment to following the science.”

“Our fourth quarter results continue to demonstrate BeiGene’s commercial capability as well as our commitment to driving operational and financial excellence,” said Julia Wang, Chief Financial Officer at BeiGene. “With our strong cash position and total product revenue reaching \$1.3 billion in 2022, BeiGene is well positioned to leverage its global scale and financial strength for long-term growth.”

#### **Fourth Quarter and Full Year 2022 Financial Results**

**Revenue** for the fourth quarter and full year 2022 was \$380.1 million and \$1.4 billion, respectively, compared to \$214.0 million and \$1.2 billion in the prior-year periods. The increase in total revenue in the quarter compared to the prior year is primarily attributable to sales of our internally developed products, BRUKINSA and tislelizumab; sales of in-licensed products from Amgen; and collaboration revenue from the Novartis agreements.

- Product revenues totaled \$339.0 million and \$1.3 billion for the fourth quarter and full year 2022, respectively, compared to \$196.8 million and \$634.0 million in the prior-year periods, and include:
  - Global sales of BRUKINSA of \$176.1 million and \$564.7 million for the fourth quarter and full year 2022, respectively, compared to \$87.6 million and \$218.0 million in the prior-year periods;
  - Sales of tislelizumab in China of \$102.2 million and \$422.9 million for the fourth quarter and full year 2022, respectively, compared to \$54.4 million and \$255.1 million in the prior-year periods;
  - Sales of Amgen in-licensed products in China of \$27.7 million and \$114.6 million for the fourth quarter and full year 2022, respectively, compared to \$20.3 million and \$58.8 million in the prior-year periods. We began selling Amgen’s BLINCYTO® (*blinatumomab*) in August 2021. Additionally, prior-year period sales do not include sales of KYPROLIS® (carfilzomib), which was launched in China in January 2022;
  - Sales of BMS in-licensed products in China of \$21.4 million and \$94.3 million for the fourth quarter and full year 2022, respectively, compared to \$29.9 million and \$89.7 million in the prior-year periods; and
- Collaboration revenue totaled \$41.1 million and \$161.3 million for the fourth quarter and full year 2022, respectively, resulting from the partial recognition of the upfront payments from Novartis related to the tislelizumab and ociperlimab agreements, which were entered into in the first and fourth quarters of 2021. This compared to \$17.2 million and \$542.3 million in the prior-year periods. Full year 2021 collaboration revenue benefited from the timing of revenue recognition from the upfront license payment from Novartis under the tislelizumab agreement.

**Cost of Sales** for the fourth quarter and full year 2022 were \$73.5 million and \$286.5 million, respectively, compared to \$48.5 million and \$164.9 million in the prior-year periods. Cost of sales increased primarily due to increased product sales of BRUKINSA and tislelizumab, as well as sales of BLINCYTO, which commenced in August 2021, and KYPROLIS and POBEVCY®, which commenced in January 2022;

**Gross Margin** as a percentage of global product sales for the fourth quarter and full year 2022 was 78.3% and 77.2%, respectively, compared to 75.3% and 74.0% in the prior-year periods. The gross margin percentage increased in both the quarter-over-quarter and year-over-year periods primarily due to a proportionally higher sales mix of global BRUKINSA sales compared to other products in our portfolio and compared to lower margin sales of in-licensed products, as well as lower costs per unit for both BRUKINSA and tislelizumab, partially offset by lower average selling prices in China for both BRUKINSA and tislelizumab.

**Operating Expenses** for the fourth quarter and full year 2022 were \$775.2 million and \$2.9 billion, respectively, compared to \$737.2 million and \$2.5 billion in the prior-year periods.

- **R&D Expenses** for the fourth quarter and full year 2022 were \$446.0 million and \$1.6 billion, respectively, compared to \$430.5 million and \$1.5 billion in the prior-year periods. The increase in R&D expenses was primarily attributable to increases in headcount and costs related to investment in our discovery and development activities, including our continued efforts to internalize research and clinical development activities, partially offset by lower fees paid to clinical research organizations (CROs) for clinical trials. Upfront fees related to in-process R&D for in-licensed assets totaled \$48.7 million and \$68.7 million in the fourth quarter and full year 2022, respectively, compared to \$30.0 million and \$83.5 million in the prior-year periods. Employee share-based compensation expense was \$35.0 million and \$139.3 million for the fourth quarter and full year 2022, respectively, compared to \$30.6 million and \$114.4 million in the prior-year periods; and
- **SG&A Expenses** for the fourth quarter and full year 2022 were \$329.0 million and \$1.3 billion, respectively, compared to \$306.5 million and \$990.1 million in the prior-year periods. The increase in SG&A expenses was primarily attributable to increased headcount, largely related to continued expansion of our commercial teams, and higher external commercial expenses, including market access studies and promotional activities. Employee share-based compensation expense was \$43.2 million and \$163.8 million for the fourth quarter and full year 2022, respectively, compared to \$32.4 million and \$126.4 million for the prior-year periods.

**Net Loss** for the fourth quarter of 2022 was \$445.3 million, or \$0.33 per share and \$4.29 per ADS, compared to \$590.7 million, or \$0.48 per share and \$6.22 per ADS in the prior year period. The decrease in net loss is primarily attributable to improved operating leverage due to growing product revenues exceeding operating expense growth. The company expects this trend to continue into 2023. Net loss for full year 2022 was \$2.0 billion, or \$1.49 per share and \$19.43 per ADS, compared to \$1.5 billion, or \$1.21 per share and \$15.71 per ADS in the prior-year period. Net loss for 2022 was unfavorably impacted by other non-operating expenses of \$223.9 million, primarily related to foreign exchange losses resulting from the strengthening of the U.S. dollar and the revaluation impact of foreign currencies held in U.S. functional currency subsidiaries. Net loss for the full year 2021 was positively impacted by the timing of revenue recognition related to the Novartis tislelizumab collaboration agreement. The company recognized \$484.6 million in the full year 2021 of the \$650.0 million upfront payment received.

**Cash, Cash Equivalents, Restricted Cash and Short-Term Investments** were \$4.5 billion as of December 31, 2022, compared to \$6.6 billion as of December 31, 2021.

- In fourth quarter of 2022, cash used in operating activities was \$318.2 million, primarily due to our net loss of \$445.3 million, offset by non-cash charges of \$127.3 million; capital expenditures were \$121.4 million; and cash used in financing activities was \$110.4 million;

In the fourth quarter of the prior year, cash used in operating activities was \$507.8 million, primarily due to our net loss of \$590.7 million, offset by non-cash charges of \$92.7 million; capital expenditures were \$115.0 million; and cash provided by financing activities was \$3.4 billion, primarily due to the STAR Market offering in December of 2021; and

- For the full year 2022, cash used in operating activities was \$1.5 billion, primarily due to our net loss of \$2.0 billion, inclusive of \$223.9 million of other losses due primarily to the strengthening of the U.S. dollar and the related revaluation of foreign currencies held by U.S. functional currency subsidiaries, non-cash charges of \$374.8 million and a decrease in our net operating assets and liabilities of \$132.4 million.

For the full year 2021, cash used in operating activities was \$1.3 billion, primarily due to our net loss of \$1.5 billion and an increase in our net operating assets and liabilities of \$118.3 million, partially offset by non-cash charges of \$277.4 million; capital expenditures were \$262.9 million; and cash provided by financing activities was \$3.6 billion, primarily due to the net proceeds from the STAR Market offering in December of 2021.

## **Recent Business Highlights**

### **Commercial Operations**

- Product sales increased 72.3% and 97.9% in the fourth quarter and full year of 2022, respectively, compared to the prior-year periods, primarily due to increased sales of our internally developed products, as well as increased sales of in-licensed products from Amgen and Bio-Thera;
- Global sales of BRUKINSA totaled \$176.1 million and \$564.7 million in the fourth quarter and full year 2022, representing growth of 101% and 159%, respectively, compared to the prior-year periods; U.S. sales of BRUKINSA totaled \$125.3 million and \$389.7 million in the fourth quarter and full year 2022, respectively, representing growth of 124% and 237%, compared to the prior-year periods. U.S. sales growth continued in the quarter, driven again by increasing uptake in mantle cell lymphoma (MCL), Waldenström's macroglobulinemia (WM), and marginal zone lymphoma (MZL). BRUKINSA sales in China totaled \$40.9 million and \$150.3 million in the fourth quarter and full year 2022, respectively, representing growth of 33% and 49% compared to the prior-year periods, driven by increases in all approved indications;

- Sales of tislelizumab in China totaled \$102.2 million and \$422.9 million in the fourth quarter and full year 2022, respectively, representing growth of 88% and 66% compared to the prior-year periods. Continued increase in new patient demand from broader reimbursement and further expansion of our salesforce and hospital listings continued to drive increased market penetration and market share for tislelizumab;
- Secured National Reimbursement Drug List (NRDL) inclusion of four additional indications in China, with nine approved tislelizumab indications now included. New indications covered as of March 1, 2023, are for:
  - Certain adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC);
  - Adult patients with advanced unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, and certain patients with advanced colorectal cancer (CRC);
  - Adult patients with locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) who have progressed after or are intolerant of prior first-line standard chemotherapy; and
  - As a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer (NPC); and
- KYPROLIS was included in the NRDL for the first time for the treatment of adult patients with R/R multiple myeloma who have received at least two prior therapies, including a proteasome inhibitor and an immunomodulatory agent. XGEVA<sup>®</sup> was successfully renewed for NRDL inclusion for the treatment of patients with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity.

## **Regulatory Progress and Development Programs**

***BRUKINSA<sup>®</sup>** (zanubrutinib), a small molecule inhibitor of Bruton's tyrosine kinase (BTK) designed to maximize BTK occupancy and minimize off-target effects, approved in more than 65 markets including the U.S., China, European Union (EU), Great Britain, Canada, Australia, South Korea and Switzerland in selected indications and under development for additional approvals globally. The global BRUKINSA development program includes more than 4,800 subjects enrolled to-date in 29 countries and regions.*

- In January 2023, announced U.S. FDA approval for the treatment of adult patients with R/R and first-line CLL/SLL;
- Announced European Commission (EC) approval for the treatment of adult patients with treatment-naïve (TN) or R/R CLL;

- Presented results from a final analysis of the Phase 3 ALPINE trial demonstrating superior PFS versus IMBRUVICA® in adult patients with R/R CLL/SLL, as assessed by an independent review committee (IRC) and investigator, as part of a late breaking abstract session at the 64th American Hematology Society (ASH) Annual Meeting, with simultaneous publication in *The New England Journal of Medicine*;
- Presented other key data from the BRUKINSA clinical development programs at ASH 2022, including an oral presentation of results from the MAGNOLIA trial in MZL and a poster with updated results in acalabrutinib-intolerant patients with B-cell malignancies;
- Announced approvals in Brazil for the treatment of adult patients with WM and adult patients with R/R MZL who have received at least one anti-CD20-based regimen;
- Received marketing authorization by the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain for the treatment of adult patients with CLL, and those with MZL who have received at least one prior anti-CD20-based therapy; and
- Expanded BRUKINSA's registration program globally, including 34 launches in 20 markets since January 1, 2022.

***Tislelizumab**, a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages; approved in China in 10 indications and under development for additional approvals globally. The global tislelizumab clinical development program includes more than 11,800 subjects enrolled to-date in 31 countries and regions.*

- Announced China National Medical Products Administration (NMPA) approval of BLA application for tislelizumab in combination with chemotherapy as a first-line treatment for patients with locally advanced unresectable or metastatic G/GEJ adenocarcinoma with high PD-L1 expression, which is the tenth approved indication in China for tislelizumab;
- Announced acceptance by the NMPA of a supplemental biologics license application (sBLA) in patients with first-line unresectable or metastatic hepatocellular carcinoma (HCC);
- Filed new drug application for tislelizumab in Brazil seeking marketing authorization for use in first – and second-line NSCLC and second-line esophageal cancer, marking BeiGene's first application for tislelizumab in Latin America; and
- Presented results from the RATIONALE-301 (NCT03412773), RATIONALE-305 (NCT03777657) and RATIONALE-306 (NCT03783442) trials at the 2023 ASCO Gastrointestinal Cancers Symposium, including positive interim overall survival (OS) data for a combination of tislelizumab and chemotherapy in first-line gastric or gastroesophageal junction (G/GEJ) cancer patients whose tumors express PD-L1.



**Ociperlimab (BGB-A1217)**, an investigational anti-TIGIT monoclonal antibody with competent Fc function. The global ociperlimab development program includes 17 countries and regions, and more than 1,600 subjects have been enrolled.

- Presented Phase 1 clinical data for checkpoint inhibitor-experienced advanced NSCLC and extensive-stage small cell lung cancer (SCLC) (NCT04047862) at ESMO-IO 2022.

**BGB-11417**, an investigational highly selective and highly potent inhibitor of BCL-2, being developed as monotherapy or in combination with zanubrutinib +/- obinutuzumab in B-cell malignancies, in combination with azacytidine in AML and MDS and as monotherapy and in combination with dexamethasone and in combination with carfilzomib in multiple myeloma. The global BGB-11417 development program includes six countries and regions, and more than 350 subjects have been enrolled.

- Presented Phase 1 clinical data for non-Hodgkin's lymphoma, CLL, acute myeloid leukemia (AML) and multiple myeloma (MM) (NCT04883957, NCT04277637, NCT04771130, and NCT04973605) at ASH 2022.

**BGB-A445**, an investigational non-ligand competing OX40 monoclonal antibody, being developed as monotherapy or in combination with tislelizumab.

- Initiated patient dosing in a Phase 2 basket trial as monotherapy and in combination with tislelizumab in melanoma, renal cell cancer (RCC) and bladder cancer (NCT05661955).

### **Early-Stage Programs**

- Continued to advance our early-stage clinical pipeline of internally developed product candidates at dose escalation stage, including:
  - BGB-B167: an investigational first-in-class CEA x 4-1BB bispecific antibody, as a monotherapy and in combination with tislelizumab in patients with selected CEA-expressing advanced or metastatic solid tumors, including colorectal cancer (CRC);
  - BGB-A425: an investigational TIM-3 antibody, in combination with tislelizumab in patients with head and neck squamous cell carcinoma (HNSCC), NSCLC and RCC;
  - BGB-15025: an investigational, first-in-class hematopoietic progenitor kinase 1 (HPK1) inhibitor as monotherapy or in combination with tislelizumab in solid tumors;
  - BGB-16673: an investigational Chimeric Degradation Activating Compound (CDAC), targeting BTK protein degradation as monotherapy in B cell malignancies;

- BGB-24714: an investigational Second Mitochondrial-derived Activator of Caspase, or SMAC, mimetic as monotherapy or in combination with paclitaxel in advanced solid tumors;
- BGB-10188: an investigational PI3K $\delta$  inhibitor as monotherapy or in combination with BRUKINSA in hematology malignancies, or in combination with tislelizumab in solid tumors; and
- BGB-23339: a potent, allosteric investigational tyrosine kinase 2 (TYK2) inhibitor.

### **Collaboration Programs**

- In collaboration with Zymeworks, announced positive topline results for a Phase 2b clinical trial of zanidatamab in advanced or metastatic HER2-amplified biliary tract cancers (NCT04466891); and
- In collaboration with Mirati, initiated patient enrollment for a Phase 2 clinical trial of sitravatinib in combination with tislelizumab in locally advanced unresectable or metastatic ESCC that progressed on or after anti-PD-(L)1 antibody therapy (NCT05461794).

### **Manufacturing Operations**

- Construction continues on the U.S. flagship manufacturing and clinical R&D facility at the Princeton West Innovation Campus in Hopewell, N.J. The property has more than one million square feet total of developable real estate, allowing for future expansion;
- Completed expansion and Good Manufacturing Practices (GMP) certification of our state-of-the-art biologics facility in Guangzhou, China, bringing total capacity to 54,000 liters with an additional expansion of 10,000 liters expected in the second quarter of 2023; and
- Continued construction on our new small molecule manufacturing campus in Suzhou, China. Phase 1 of construction is expected to add more than 559,000 square feet and expand production capacity to 600 million tablets/capsules, and to be completed in 2023. Once completed, qualified and approved, the total production capacity is expected to increase our small molecule manufacturing capability in China by up to 10 times current capacity.

### **Corporate Developments**

- Announced the launch of the *Talk About It: Cancer and Mental Health* program, designed to elevate the important intersection of mental health and cancer care to help improve health outcomes for cancer patients.

## **Expected Milestones**

### ***BRUKINSA***

- Submit supplemental New Drug Applications (sNDA) in the U.S. and EU in the first half of 2023 for PFS superiority versus IMBRUVICA in R/R CLL/SLL, as demonstrated in the Phase 3 ALPINE trial;
- Continue to support NMPA review of sNDA for first-line CLL/SLL and WM in China, with a decision expected in the first half of 2023;
- Continue to support Health Canada and Australian Therapeutic Goods Administration (TGA) reviews of sNDAs for CLL, with decisions expected in 2023; and
- Continue to expand BRUKINSA's registration program globally in new geographies and indications.

### ***Tislelizumab***

- Continue to support NMPA review of BLA applications for tislelizumab in combination with chemotherapy as a first-line treatment in patients with unresectable locally advanced, recurrent or metastatic ESCC, with a decision expected in the first half of 2023; and for tislelizumab as a treatment for first-line hepatocellular carcinoma, with a decision expected in the second half of 2023;
- Continue to support review by regulatory authorities of BeiGene's applications for tislelizumab, including:
  - Australia's TGA review of BLA for tislelizumab in first – and second-line NSCLC and second-line ESCC, with a decision expected in the second half of 2023, as well as New Zealand's Medsafe review of BLA for tislelizumab in first – and second-line NSCLC and second-line ESCC; and
  - South Korea's MFDS review of BLA for tislelizumab in second-line ESCC;
- In collaboration with Novartis, continue to support review of marketing applications, including:
  - Ongoing FDA review of the BLA submission in second-line ESCC, including facilitating the scheduling of required inspections as soon as possible, with a decision expected in 2023;
  - European Medicines Agency (EMA) review of marketing authorization applications for tislelizumab in first – and second-line NSCLC and second-line ESCC, with a decision expected in 2023;

- MHRA review of tislelizumab for treatment of first – and second-line NSCLC and second-line ESCC in Great Britain;
  - Swissmedic review of marketing authorization applications for tislelizumab in second-line ESCC and second-line NSCLC;
  - Support U.S. FDA regulatory submission by Novartis in 2023 for first-line gastric cancer and first-line unresectable ESCC;
  - Submit BLA to Japan’s Pharmaceutical and Medical Devices Agency (PMDA) in 2023 for first – and second-line ESCC; and
- Announce final analysis data from pivotal trials in extensive-stage small cell lung cancer and first-line gastric cancer in 2023.

***BGB-11417 (BCL-2)***

- Initiate global pivotal trial in first-line CLL in combination with BRUKINSA in the second half of 2023; and
- Announce readouts from ongoing studies.

***Ociperlimab (TIGIT)***

- Announce readouts for multiple Phase 2 studies in 2023, including:
  - For second-line ESCC in patients whose tumors express PD-(L)1 (NCT04732494);
  - For first-line HCC (NCT04948697);
  - For first-line NSCLC (NCT05014815); and
- Complete enrollment in the Phase 3 AdvanTIG-302 trial in first-line NSCLC in 2023.

***BGB-16673 (BTK CDAC)***

- Initial data readouts for Phase 1 studies in B cell malignancies (NCT05006716, NCT05294731) in 2023.

***BGB-A445 (OX 40)***

- Initial data readout for Phase 1 study in solid tumors (NCT04215978) in 2023.

### ***BGB-15025 (HPK 1)***

- Initiate dose expansion in combination with tislelizumab in solid tumors (NCT04649385) in 2023.

### ***Collaboration Programs***

- In collaboration with Leads Biolabs, initiate patient dosing of LBL-007, a novel investigational antibody targeting the LAG-3 pathway, in combination with tislelizumab, in umbrella studies comparing different tislelizumab combination regimens, including with BGB-A445 and ociperlimab (NCT05635708, NCT05577702), in 2023.

### **COVID-19 Impact and Response**

We expect that the worldwide health crisis of COVID-19 will continue to have a negative impact on our operations, including commercial sales, regulatory interactions, inspections, filings, manufacturing, and clinical trial recruitment, participation, and data readouts. There remains uncertainty regarding the future impact of the pandemic both globally and specifically in China due to outbreaks and restrictions and potential impact on clinical, manufacturing and commercial operations. We are striving to minimize delays and disruptions, have put protocols and procedures in place, and continue to execute on our commercial, regulatory, manufacturing, and clinical development goals globally.

## Financial Summary

### Select Condensed Consolidated Balance Sheet Data (U.S. GAAP)

(Amounts in thousands of U.S. Dollars)

	As of	
	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021<sup>1</sup></u>
	(audited)	
<b>Assets:</b>		
Cash, cash equivalents, restricted cash and short-term investments	\$4,540,288	\$6,624,849
Accounts receivable	173,168	483,113
Property and equipment, net	845,946	587,605
Total assets	\$6,379,290	\$8,535,525
<b>Liabilities and equity:</b>		
Accounts payable	\$294,781	\$262,400
Accrued expenses and other payables	467,352	558,055
Deferred revenue	255,887	407,703
R&D cost share liability	293,960	390,362
Debt	538,117	629,678
Total liabilities	1,995,935	2,402,962
Total equity	\$4,383,355	\$6,132,563

## Condensed Consolidated Statements of Operations (U.S. GAAP)

(Amounts in thousands of U.S. dollars, except for shares, American Depositary Shares (ADSs), per share and per ADS data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021 <sup>1</sup>	2022	2021 <sup>1</sup>
	(unaudited)		(audited)	
Revenue:				
Product revenue, net	\$339,022	\$196,785	\$1,254,612	\$633,987
Collaboration revenue	41,073	17,194	161,309	542,296
Total revenues	380,095	213,979	1,415,921	1,176,283
Expenses:				
Cost of sales – products	73,522	48,545	286,475	164,906
Research and development	446,023	430,485	1,640,508	1,459,239
Selling, general and administrative	328,984	306,501	1,277,852	990,123
Amortization of intangible assets	188	187	751	750
Total expenses	848,717	785,718	3,205,586	2,615,018
Loss from operations	(468,622)	(571,739)	(1,789,665)	(1,438,735)
Interest (expense) income, net	18,219	(4,482)	52,480	(15,757)
Other (expense) income, net	19,438	(10,583)	(223,852)	15,904
Loss before income taxes	(430,965)	(586,804)	(1,961,037)	(1,438,588)
Income tax expense	14,370	3,874	42,778	19,228
Net loss	(445,335)	(590,678)	(2,003,815)	(1,457,816)
Less: Net loss attributable to noncontrolling interest	–	–	–	–
Net loss attributable to BeiGene, Ltd.	<u>\$(445,335)</u>	<u>\$(590,678)</u>	<u>\$(2,003,815)</u>	<u>\$(1,457,816)</u>
Net loss per share attributable to BeiGene, Ltd., basic and diluted	<u>\$(0.33)</u>	<u>\$(0.48)</u>	<u>\$(1.49)</u>	<u>\$(1.21)</u>
Weighted-average shares outstanding, basic and diluted	<u>1,348,916,108</u>	<u>1,235,346,414</u>	<u>1,340,729,572</u>	<u>1,206,210,049</u>
Net loss per ADS attributable to BeiGene, Ltd., basic and diluted	<u>\$(4.29)</u>	<u>\$(6.22)</u>	<u>\$(19.43)</u>	<u>\$(15.71)</u>
Weighted-average ADSs outstanding, basic and diluted	<u>103,762,778</u>	<u>95,026,647</u>	<u>103,133,044</u>	<u>92,785,388</u>

1 We revised certain prior period financial statements for an error related to the valuation of net deferred tax assets, the impact of which was immaterial to our previously filed financial statements in the first and second quarter of 2022 and the quarterly and annual periods of fiscal 2021 (see “Notes to the Consolidated Financial Statements, Note. 2 Summary of Significant Accounting Policies” and “Note 3. Revision of Prior Period Financial Statements” included in our Annual Report on Form 10-K for the fiscal year ended 2022.

## **About BeiGene**

BeiGene is a global biotechnology company that is developing and commercializing innovative and affordable oncology medicines to improve treatment outcomes and access for far more patients worldwide. With a broad portfolio, we are expediting development of our diverse pipeline of novel therapeutics through our internal capabilities and collaborations. We are committed to radically improving access to medicines for far more patients who need them. Our growing global team of more than 9,000 colleagues spans five continents, with administrative offices in Basel; Beijing; and Cambridge, U.S. To learn more about BeiGene, please visit [www.beigene.com](http://www.beigene.com) and follow us on Twitter at @BeiGeneGlobal.

## **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding clinical data for BeiGene's drug candidates and approvals of its medicines; the conduct of late-stage clinical trials and expected data readouts; additional planned product approvals and launches; the advancement of and anticipated clinical development, regulatory approvals and other milestones and commercialization of BeiGene's medicines and drug candidates; the potential for BRUKINSA to provide clinical benefit to patients with CLL compared with the comparator drug; the success of BeiGene's commercialization efforts and revenue growth; the expected capacities and completion dates for the Company's manufacturing facilities under construction; the impact of the COVID-19 pandemic on the Company's clinical development, regulatory, commercial, manufacturing, and other operations; BeiGene's plans and the expected events and milestones under the captions "Recent Business Highlights" and "Expected Milestones"; and BeiGene's plans, commitments, aspirations and goals under the caption "About BeiGene". Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene's ability to obtain and



maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing, commercialization, and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial, manufacturing, and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

**Investor Contact**

Kevin Mannix

+1857-302-5189

[ir@beigene.com](mailto:ir@beigene.com)

**Media Contact**

Kyle Blankenship

+1667-351-5176

[media@beigene.com](mailto:media@beigene.com)

---

BLINCYTO<sup>®</sup>, KYPROLIS<sup>®</sup> and XGEVA<sup>®</sup> are registered trademarks of Amgen.

POBEVCY<sup>®</sup> is a registered trademark of Bio-Thera Solutions, Ltd.

IMBRUVICA<sup>®</sup> is a registered trademark of Pharmacyclics LLC and Janssen Biotech, Inc.