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 AND NINE MONTHS ENDED SEPTEMBER 30, 2023 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 condensed consolidated financial results for the three and nine months ended September 30, 2023 and business updates.

The Company is pleased to announce the unaudited condensed consolidated results of the Company and its subsidiaries for the three and nine months ended September 30, 2023 (the "**Q3 Results**") published in accordance with applicable rules of the U.S. Securities and Exchange Commission and key business and pipeline highlights for the third quarter of 2023 and expected upcoming milestones (the "**Business Updates**").

The Q3 Results have been prepared in accordance with U.S. Generally Accepted Accounting Principles, which are different from the International Financial Reporting Standards.

Attached hereto as Schedule 1 is the full text of the press release issued by the Company on November 9, 2023 (U.S. Eastern Time), in relation to the Q3 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.

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 the ability of BeiGene to execute on its global growth strategy; the advancement of and anticipated clinical activities, regulatory submissions and approvals of BeiGene's medicines and drug candidates; BeiGene's plans and the expected events and milestones under the caption "Anticipated Upcoming Milestones"; the expected capacities and completion dates for the Company's manufacturing facilities under construction and the potential for such facilities to increase manufacturing capabilities; 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; and 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 Q3 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, November 10, 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 as Non-executive Director, and Dr. Margaret Han Dugan, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Anthony C. Hooper, 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 Continues Global Growth with Third Quarter 2023 Financial Results and Business Updates

- *Generated total revenue of $781 million and global product sales of $595 million, a 102% and 70% increase from the prior-year period, respectively, while steadily improving operating leverage*

- *Global sales of BRUKINSA totaled $358 million, a 130% increase from the prior-year period, driven by launches in the U.S. and Europe*

- *First TEVIMBRA approval in EU for 2L esophageal squamous cell carcinoma (ESCC) accelerates global regulatory strategy for cornerstone therapy*

BASEL, Switzerland; BEIJING; and CAMBRIDGE, Mass. – (BUSINESS WIRE) – BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today reported financial results from the third quarter of 2023 and business highlights.

"Our BeiGene team delivered another strong quarter across our global product portfolio, driven by the ongoing successful launch of BRUKINSA, where we continue to see rapid uptake across all approved indications, including CLL," said John V. Oyler, Chairman, Co-Founder and CEO at BeiGene. "We are excited to have regained the rights to TEVIMBRA worldwide, which is now approved in the EU and under regulatory review in 10 additional markets. We are now better positioned than ever before to execute on our global growth strategy while steadily improving operating leverage with moderate expense growth."

Key Business and Pipeline Highlights

- Generated global sales of BRUKINSA of $357.7 million, an increase of 130% compared with the prior-year period, as global launch momentum continues across multiple indications, including chronic lymphocytic leukemia (CLL);

- Received a positive opinion from the European Committee for Health and Medicinal Products (CHMP) of the European Medicines Agency for BRUKINSA for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) who have received at least two prior systematic treatments;

- Received positive guidance from the National Institute for Health and Care Excellence for reimbursement of BRUKINSA on the National Health Service in England and Wales for the treatment of adult patients with R/R CLL;

- Regained global rights to the development, manufacture and commercialization of TEVIMBRA, strengthening the Company's global portfolio in solid tumors;

- Announced European Commission (EC) approval of TEVIMBRA as monotherapy for the treatment of adult patients with unresectable, locally advanced or metastatic ESCC after prior platinum-based chemotherapy; and

- Announced U.S. Food and Drug Administration (FDA) acceptance for review of a Biologics License Application (BLA) for tislelizumab as a first-line treatment for patients with unresectable, recurrent, locally advanced, or metastatic ESCC with a target action date in July 2024, under the Prescription Drug User Fee Act (PDUFA).

Third Quarter 2023 Financial Highlights

Total Revenue for the three months ended September 30, 2023, was $781.3 million, compared to $387.6 million in the same period of 2022, representing 101.6% growth, driven by growth in product revenue and the recognition of remaining deferred revenues from the Novartis collaborations. Total revenue by geographic area is presented as follows (amounts in thousands of U.S. dollars) [(1)]:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	$	$	$	$
United States – total revenue	**398,229**	**133,431**	**815,059**	**347,180**
Product revenue	270,084	108,104	632,391	264,373
Collaboration revenue	128,145	25,327	182,668	82,807
China – total revenue	**287,935**	**233,077**	**831,399**	**636,241**
Product revenue	284,981	233,077	825,809	636,241
Collaboration revenue	2,954	–	5,590	–
Europe – total revenue	**85,583**	**17,995**	**153,273**	**46,634**
Product revenue	30,664	5,200	76,487	9,205
Collaboration revenue	54,919	12,795	76,786	37,429
Rest of world – product revenue	**9,561**	**3,125**	**24,639**	**5,771**
Total Revenue	**781,308**	**387,628**	**1,824,370**	**1,035,826**

(1) Net product revenues by geographic area are based upon the location of the customer, and net collaboration revenue is recorded in the jurisdiction in which the related income is expected to be sourced from.

Product Revenue for the three months ended September 30, 2023, was $595.3 million, compared to $349.5 million in the same period of 2022, representing 70.3% growth;

- Product sales increased $245.8 million in the third quarter of 2023 compared to the prior-year period, primarily due to increased sales of our internally developed products, BRUKINSA and tislelizumab, as well as increased sales of in-licensed products from Amgen;

- U.S. sales of BRUKINSA totaled $270.1 million in the third quarter of 2023, representing growth of 149.8% over the prior-year period, as BRUKINSA continued to gain share across both TN and R/R adult patients with CLL or small lymphocytic lymphoma (SLL) and providers expanded adoption of all FDA-approved indications. BRUKINSA sales in China totaled $47.4 million, representing growth of 20.8% over the prior-year period, driven by increases in all approved indications as the Company continues to increase market value share as the Bruton's tyrosine kinase inhibitor (BTKi) leader in China;

- Sales of tislelizumab in China totaled $144.4 million in the third quarter of 2023, representing growth of 12.6% compared to the prior-year period. Continued increase in new patient demand from reimbursement of new indications and further expansion of our salesforce efficiency and hospital listings continued to drive increased market penetration and leading PD-1 inhibitor market share for tislelizumab. Market share for tislelizumab continued to grow, despite a market slowdown in China during the quarter.

Gross Margin as a percentage of global product revenue for the third quarter of 2023 was 83.8%, compared to 78.1% in the prior-year period. The gross margin percentage increased primarily due to proportionally higher sales mix of global BRUKINSA compared to other products in the portfolio and compared to lower-margin sales of in-licensed products, as well as lower costs per unit for tislelizumab due to increased volume.

Operating Expenses for the three months ended September 30, 2023, were $819.0 million, compared to $749.4 million in the same period of 2022, representing 9.3% growth, primarily due to increased internal costs for research and development and sales and marketing costs in the U.S. and Europe, compared to the prior-year period. The Company expects product revenue growth to continue to meaningfully outpace operating expense growth, generating continued operating leverage.

Net Income for the quarter ended September 30, 2023, was $215.4 million compared to net loss of $557.6 million in the same period of 2022. The improvement in net income compared to the prior year period was primarily attributable to reduced operating losses and the non-operating gain of $362.9 million related to the BMS arbitration settlement. Operating loss improved $304.4 million compared to the prior-year period, as our product revenue growth and management of expenses is driving increased operating leverage. In addition, the reacquisition of the full global commercial rights to ociperlimab and TEVIMBRA resulted in the recognition of the remaining deferred collaboration revenue, which increased our total revenue.

For the quarter ended September 30, 2023, basic and diluted earnings per share were $0.16 and $0.15, respectively, and basic and diluted earnings per American Depositary Share (ADS) were $2.06 and $2.01, respectively. For the quarter ended September 30, 2022, net loss per share was $0.41 per share, and $5.39 per ADS.

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were $3.2 billion as of September 30, 2023, and $4.5 billion as of December 31, 2022.

Cash used in operations for the quarter ended September 30, 2023 totaled $78.2 million compared to $561.9 million in the prior-year period, driven by improved operating leverage.

For further details on BeiGene's Third Quarter 2023 Financial Statements, please see BeiGene's Quarterly Report on Form 10-Q for the third quarter of 2023 filed with the U.S. Securities and Exchange Commission.

Regulatory Progress and Development Programs

Category	Asset	Recent Milestones
Approvals/Regulatory Updates	*BRUKINSA*	• Received approval of an updated label in the EU and UK for superior progression-free survival (PFS) versus ibrutinib for the treatment of R/R CLL based on results from the Phase 3 ALPINE trial • Received a positive CHMP opinion recommending approval in combination with obinutuzumab for the treatment of adult patients with R/R FL who have received at least two prior lines of systemic therapy • Received regulatory approvals in 13 markets for the treatment of TN and R/R CLL • Received Swissmedic approval for the treatment of R/R CLL • Received first approval in Malaysia for the treatment of R/R Waldenström's macroglobulinemia (WM) • Received U.S. FDA approval of BeiGene Suzhou as an alternative drug product manufacturing site
	TEVIMBRA	• Received EC approval as monotherapy for the treatment of adult patients with unresectable, locally advanced or metastatic ESCC after prior platinum-based chemotherapy
	BAITUOWEI® (Goserelin Microspheres for Injection)	• In partnership with Luye Pharma, received China National Medicinal Products Administration (NMPA) approval for the treatment of breast cancer in premenopausal and perimenopausal women eligible for hormone therapy
Regulatory Submissions	*Tislelizumab*	• Received U.S. FDA acceptance of BLA submission for the treatment of first-line ESCC patients in combination with chemotherapy, with a target PDUFA action date in July 2024 • Received NMPA acceptance of a supplemental Biologics License Application (sBLA) submission as a combination therapy for the treatment of first-line gastric cancer patients regardless of PD-(L)1 expression • Received NMPA acceptance of an sBLA for the treatment of first-line extensive-stage small-cell lung cancer (ES-SCLC)
Clinical Activities	*Tislelizumab*	Announced positive event-free survival (EFS) readout from the Phase 3 RATIONALE 315 trial comparing neoadjuvant treatment or placebo plus platinum-based chemotherapy followed by adjuvant treatment or placebo in resectable stage II or IIIA non-small cell lung cancer (NSCLC)
	Sonrotoclax (BGB-11417)	• Initiated global potentially registration enabling pivotal trial in R/R WM
	Early development	• Enrolled first patients in Phase 1 clinical trials for four New Molecular Entities (NME), including BCL2i 2G*, CCR8 mAb, DGK and HPK1 2G*

* *Second generation*

Anticipated Upcoming Milestones

Category	Asset	Anticipated Milestone
Approvals/ Regulatory Updates	*BRUKINSA*	• Receive U.S. FDA approval of an sNDA for PFS superiority in R/R CLL/SLL in the fourth quarter of 2023 based on results from the Phase 3 ALPINE trial • Receive U.S. FDA approval of an sNDA in combination with obinutuzumab for the treatment of adult patients with R/R FL who have received two prior lines of systemic therapy in March 2024
	Tislelizumab	• Receive U.S. FDA approval for the treatment of adult patients with second-line ESCC in U.S. in 2023 or first half of 2024 • Receive U.S. FDA approval for the treatment of patients with first-line unresectable, recurrent, locally advanced, or metastatic ESCC with a target PDUFA action date in July 2024 • Receive EMA approval in combination with chemotherapy for the first-line treatment of metastatic NSCLC and in the second line in the first half of 2024
Regulatory Submissions	*Tislelizumab*	• Submit an sBLA with the U.S. FDA for the treatment of first-line gastric cancer in 2023 • Submit an application for marketing and manufacturing approval with the Japan PMDA for the treatment of first- and second-line ESCC in the first half of 2024 • Submit an sBLA with the China NMPA for neoadjuvant treatment plus platinum-based chemotherapy followed by adjuvant treatment of adult patients with resectable Stage II or IIIA NSCLC in the first half of 2024 • Submit an sBLA with the EMA for the treatment of adult patients with first-line ESCC in the first quarter of 2024
Clinical Activities/ Data Readouts	*BRUKINSA*	• Announce additional follow-up data from the Phase 3 ALPINE study versus IMBRUVICA in R/R CLL/SLL in the fourth quarter of 2023
	Sonrotoclax	• Initiate global pivotal trial in combination with BRUKINSA in first-line CLL in the fourth quarter of 2023
	BTK CDAC (BGB-1663)	• Announce first data readouts from Phase 1 study in B-cell malignancies at ASH in December 2023
	Ociperlimab (Anti-TIGIT)	• Complete enrollment in the Phase 3 AdvanTIG-302 trial in first-line NSCLC in the first quarter of 2024

Scientific Congress Updates

- Will present 24 accepted abstracts at the American Society of Hematology (ASH) 2023 Annual Meeting in December, including long-term follow-up data from the Phase 3 ALPINE trial of BRUKINSA versus ibrutinib in adult patients with R/R CLL/SLL and clinical data from a Phase 1/2 clinical trial of BRUKINSA in combination with sonrotoclax in TN CLL;

- Presented 10 abstracts, including five oral presentations, at the European Society for Medical Oncology (ESMO) 2023 Congress, highlighted by:

    - Final analysis results from the global, Phase 3 RATIONALE-305 study evaluating tislelizumab in combination with chemotherapy as a first-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma (GC/GEJC); and

    - Final analysis of pathological response to neoadjuvant tislelizumab in combination with chemotherapy in patients with resectable Stage II-IIIA non-small cell lung cancer (NSCLC) in results from the Phase 3 RATIONALE-315 study;

- Presented final analysis data from the Phase 3 RATIONALE-312 trial for tislelizumab in combination with chemotherapy versus chemotherapy alone for the first-line treatment of adult patients with ES-SCLC at the 2023 World Conference on Lung Cancer.

Manufacturing Operations

- Entered final phase of construction at U.S. flagship manufacturing and clinical R&D facility at the Princeton West Innovation Campus in Hopewell, N.J. The property has more than 1 million square feet of total developable real estate, allowing for future expansion; the site will be operational in summer 2024;

- Neared completion on construction of an ADC production facility and additional biologics clinical production capabilities at our state-of-the-art biologics facility in Guangzhou, China, which has a current total capacity of 64,000 liters; and

- This month, will complete 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 per year; once completed, qualified and approved, it is expected to increase the current small molecule manufacturing capacity in China by more than 5 times.

Corporate Developments

- Terminated a License and Collaboration Agreement with Zymeworks for the clinical development and commercialization of its investigational HER2-targeted bispecific antibody drug conjugate, ZW49 (zanidatamab zovodotin), in Asia (excluding Japan), Australia and New Zealand.

Financial Summary

Select Condensed Consolidated Balance Sheet Data (U.S. GAAP)
(Amounts in thousands of U.S. Dollars)

	As of	
	September 30, 2023	**December 31, 2022**
	(unaudited)	**(audited)**
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 3,187,881	$ 4,540,288
Accounts receivable, net	309,079	173,168
Inventories	316,929	282,346
Property, plant and equipment, net	1,178,038	845,946
Total assets	5,524,879	6,379,290
Liabilities and equity:		
Accounts payable	341,857	294,781
Accrued expenses and other payables	505,824	467,352
Deferred revenue	300	255,887
R&D cost share liability	255,391	293,960
Debt	531,051	538,117
Total liabilities	1,761,645	1,995,935
Total shareholder's equity	$ 3,763,234	$ 4,383,355

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	
Revenue:				
Product revenue, net	$ 595,290	$ 349,506	$ 1,559,326	$ 915,590
Collaboration revenue	186,018	38,122	265,044	120,236
Total revenues	781,308	387,628	1,824,370	1,035,826
Expenses:				
Cost of sales – products	96,309	76,543	274,088	212,953
Research and development	453,259	426,363	1,284,607	1,194,485
Selling, general and administrative	364,421	322,892	1,087,954	948,868
Amortization of intangible assets	1,287	187	1,662	563
Total expenses	915,276	825,985	2,648,311	2,356,869
Loss from operations	(133,968)	(438,357)	(823,941)	(1,321,043)
Interest income, net	26,649	12,759	57,735	34,261
Other income (expense), net	336,657	(125,640)	291,142	(243,290)
Income (loss) before income taxes	229,338	(551,238)	(475,064)	(1,530,072)
Income tax expense	13,925	6,318	39,091	28,408
Net income (loss)	215,413	(557,556)	(514,155)	(1,558,480)
Net income (loss) per share attributable to BeiGene, Ltd.:				
Basic	$ 0.16	$ (0.41)	$ (0.38)	$ (1.16)
Diluted	$ 0.15	$ (0.41)	$ (0.38)	$ (1.16)
Weighted-average shares outstanding:				
Basic	1,360,716,279	1,345,303,747	1,358,392,470	1,337,976,853
Diluted	1,390,331,833	1,345,303,747	1,358,392,470	1,337,976,853
Net income (loss) per ADS attributable to BeiGene, Ltd.:				
Basic	$ 2.06	$ (5.39)	$ (4.92)	$ (15.14)
Diluted	$ 2.01	$ (5.39)	$ (4.92)	$ (15.14)
Weighted-average ADSs outstanding:				
Basic	104,670,483	103,484,904	104,491,728	102,921,296
Diluted	106,948,603	103,484,904	104,491,728	102,921,296

About BeiGene

BeiGene is a global biotechnology company that is discovering and developing innovative oncology treatments that are more affordable and accessible to cancer 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 10,000 colleagues spans five continents, with administrative offices in Basel, Beijing, and Cambridge, U.S. To learn more about BeiGene, please visit www.beigene.com and follow us on LinkedIn and X (formerly known as Twitter).

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 the ability of BeiGene to execute on its global growth strategy; the advancement of and anticipated clinical activities, regulatory submissions and approvals of BeiGene's medicines and drug candidates; BeiGene's plans and the expected events and milestones under the caption "Anticipated Upcoming Milestones"; the expected capacities and completion dates for the Company's manufacturing facilities under construction and the potential for such facilities to increase manufacturing capabilities; 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; and 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.

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