BeiGene Accelerates Global Momentum with Strong Second Quarter 2023 Financial Results

- *Recorded total product revenue of $554 million in the quarter, an increase of 82% from the prior-year period, driven by increased sales of BRUKINSA® worldwide*

- *Global sales of BRUKINSA totaled $308 million in the quarter, a 139% increase from the prior-year period and a 46% increase from the prior quarter; continued execution on launch of BRUKINSA in the U.S. and Europe for the treatment of adult patients with chronic lymphocytic leukemia (CLL), strengthening its position as the BTK inhibitor of choice*

- *Hosted investor R&D Day highlighting growing and diverse pipeline of innovative therapies as well as differentiated discovery and development strategy*

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 second quarter of 2023 and business highlights.

"Our strong second quarter results highlight the continued execution of our global commercial teams and the success of our two cornerstone medicines, BRUKINSA and tislelizumab. As demonstrated by the growing prescriber use for patients with CLL, BRUKINSA is becoming the BTK inhibitor of choice, driven by compelling efficacy and safety data across indications, including superiority versus IMBRUVICA® in relapsed/refractory (R/R) CLL," said John V. Oyler, Co-Founder, Chairman and CEO at BeiGene. "Our robust pipeline, highlighted at our recent investor R&D Day and fueled by one of the largest and most productive oncology research teams in the industry, will continue to drive our short- and long-term growth as a science-based organization, and allow us to fulfill our mission of providing innovative cancer medicines and improving treatment options for more patients around the world."

Key Business and Pipeline Highlights

- Received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for tislelizumab as a monotherapy for the treatment of adult patients with unresectable, locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) after prior platinum-based chemotherapy;

- Announced U.S. Food and Drug Administration (FDA) acceptance of a supplemental new drug application (sNDA) for BRUKINSA in combination with GAZYVA® (obinutuzumab) as a treatment for patients with R/R follicular lymphoma (FL) with a target action date in the first quarter of 2024, under the Prescription Drug User Fee Act;

- Announced Health Canada approval of BRUKINSA for the treatment of adult patients with CLL, and Australia Therapeutic Goods Administration (TGA) approval of BRUKINSA for the treatment of treatment-naïve (TN) and R/R CLL/small lymphocytic lymphoma (SLL);

- Announced new regulatory approvals for BRUKINSA, including China National Medicinal Products Administration (NMPA) approval of two sNDAs for TN adults with CLL or SLL and Waldenström's macroglobulinemia (WM), and two sNDAs for conversions from conditional approval to regular approval for certain patients with R/R CLL/SLL and R/R WM;

- Held investor R&D Day, highlighting the Company's growing and diverse pipeline of innovative therapies. For webcast replay and more information from the event, visit the investors section of the BeiGene website at http://ir.beigene.com; https://hkexir.beigene.com; or https://sseir.beigene.com;

- Announced an agreement with DualityBio for BeiGene to acquire an exclusive option for a global clinical and commercial license to an investigational, preclinical Antibody Drug Conjugate (ADC) therapy for patients with select solid tumors to complement the Company's initial internally discovered ADC assets, and;
- Announced a partnership with The Max Foundation, a global nonprofit organization dedicated to accelerating health equity by delivering medication, technology, and supportive services to patients worldwide, and the BeiGene Foundation, to provide access to BRUKINSA for the treatment of adult patients with CLL in 29 countries over the next three years, enabling the Company's mission to treat more patients globally.

Second Quarter 2023 Financial Highlights

Product Revenue for the three months ended June 30, 2023, was $553.7 million, compared to $304.5 million in the same period of 2022, representing 81.8% growth;

- Product sales increased $249.2 million in the second 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 $223.5 million in the second quarter, representing growth of 152.9% over the prior-year period, as adoption for adult patients with CLL/SLL accelerated and use across all FDA-approved indications continued to expand. BRUKINSA sales in China totaled $48.5 million, representing growth of 32.2% over the prior-year period, driven by increases in all approved indications as the Company continues to increase market value share as the BTK leader in China;
- Sales of tislelizumab in China totaled $149.5 million for the second quarter of 2023, representing growth of 42.5% 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, and;
- Total product revenues by geographic area are presented as follows (amounts in thousands of U.S. dollars):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	$	$	$	$
China	293,919	212,429	540,828	403,164
United States	223,540	88,381	362,307	156,269
Rest of world	36,286	3,701	60,901	6,651
Total	553,745	304,511	964,036	566,084

Gross Margin as a percentage of global product revenue for the second quarter of 2023 was 82.7%, compared to 76.6% in the prior-year period. The gross margin percentage increased primarily due to lower costs per unit for both

BRUKINSA and tislelizumab, as well as a proportionally higher sales mix of global BRUKINSA compared to other products in the portfolio and compared to lower-margin sales of in-licensed products.

Operating Expenses for the three months ended June 30, 2023, were $818.0 million, compared to $709.8 million in the same period of 2022, representing 15.2% growth in comparison to 81.8% product revenue growth in the quarter, driving significant operating leverage.

Net Loss for the quarter ended June 30, 2023, was $381.1 million, or $0.28 per share, and $3.64 per American Depositary Share (ADS), compared to $565.7 million, or $0.42 per share, and $5.50 per ADS in the same period of 2022. The decrease in net loss is primarily attributable to improved operating leverage due to product revenue growth exceeding operating expense growth. The Company expects this trend to continue through 2023. Net loss for the quarter was negatively impacted by other non-operating expenses of $63.8 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. Non-operating expenses were $129.6 million in the same period of 2022.

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were $3.5 billion as of June 30, 2023, and $4.5 billion as of December 31, 2022.

For further details on BeiGene's Second Quarter 2023 Financial Statements, please see BeiGene's Quarterly Report on Form 10-Q for the second 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 (zanubrutinib)*	• Health Canada approval for the treatment of adult patients with CLL/SLL • Australia TGA approval for the treatment of TN and R/R CLL/SLL • China NMPA approval of: o sNDA for the treatment of TN adult patients with CLL/SLL o sNDA for the treatment of adult patients with TN WM o sNDA for the conversion from conditional to regular approval for the treatment of adult patients with R/R CLL/SLL o sNDA for the conversion from conditional to regular approval for the treatment of adult patients with R/R WM
	Tislelizumab	• EU CHMP positive opinion for tislelizumab as a monotherapy for the treatment of adult patients with unresectable, locally advanced or metastatic ESCC after prior platinum-based chemotherapy • China NMPA approval of: o sNDA for the treatment of adult patients with first-line gastric cancer (PD-L1+) o sNDA for the treatment of adult patients with first-line ESCC

	BAITUOWEI® (Goserelin Microspheres for Injection)	• In partnership with Luye Pharma, China NMPA approval for the treatment of patients with prostate cancer requiring androgen deprivation therapy
Regulatory Submissions	*BRUKINSA*	• Received U.S. FDA acceptance of sNDA for the treatment of adult patients with R/R FL • Received EMA acceptance of marketing authorization application for the treatment of adult patients with R/R FL
Clinical Activities	*BRUKINSA*	• First subject enrolled in a Phase 3 clinical trial for primary membranous nephropathy

Anticipated Upcoming Milestones

Category	Asset	Anticipated Milestone
Approvals/Regulatory Updates	*Tislelizumab*	• In partnership with Novartis, approval for second-line ESCC in U.S.* and EU
Regulatory Submissions	*Tislelizumab*	• First-line extensive stage small cell lung cancer (ES-SCLC) submission in China • In partnership with Novartis for first-line ESCC in U.S. and EU • In partnership with Novartis to first-line gastric cancer in U.S. and EU • In partnership with Novartis for first- and second-line ESCC in Japan
Clinical Activities/Data Readouts	*BRUKINSA*	• Announce additional follow-up data from the Phase 3 ALPINE study versus ibrutinib in R/R CLL
	Tislelizumab	• Announce results from the Phase 3 RATIONALE-315 trial in neoadjuvant and adjuvant non-small cell lung cancer (NSCLC)
	Sonrotoclax (BGB-11417, BCL-2 inhibitor)	• Initiate global pivotal trial in combination with BRUKINSA in first-line CLL in the second half of 2023 • Initiate global potential registration enabling trial in R/R WM in the second half of 2023 • Announce additional data from Phase 1 studies
	BTK CDAC (BGB-1663)	• Announce updated data readouts from Phase 1 studies in B-cell malignancies
	Ociperlimab (Anti-TIGIT)	• Complete enrollment in the Phase 3 AdvanTIG-302 trial in first-line NSCLC in 2023 • Announce data for multiple Phase 2 studies, including:

* Original PDUFA date deferred

		○ For second-line ESCC in patients whose tumors express PD-(L)1 ○ For first-line hepatocellular carcinoma (HCC) ○ For first-line NSCLC

Scientific Congress Updates

- Present results from the Phase 3 RATIONALE-312 trial investigating tislelizumab with or without chemotherapy as a treatment for extensive-stage small cell lung cancer as an oral presentation at the 2023 World Conference on Lung Cancer in September;

- Present eight accepted abstracts, including data from the tislelizumab, ociperlimab and other Solid Tumor programs, at the European Society of Medical Oncology (ESMO) Annual Meeting in October;

- Presented clinical results for BRUKINSA at the American Society of Clinical Oncology (ASCO) Annual Meeting and European Hematology Association (EHA) congress, including Phase 1 results in R/R diffuse large B-cell lymphoma (DLBCL) and updated results from the Phase 3 ROSEWOOD study in combination with GAZYVA in R/R FL;

- Presented two abstracts for tislelizumab at the ASCO Annual Meeting, including additional analyses from the Phase 3 RATIONALE-301 trial versus sorafenib in first-line unresectable HCC;

- Presented results from a Phase 1 study of internally discovered OX40 agonist BGB-A445, with or without tislelizumab, in patients with advanced solid tumors at ASCO; and

- In partnership with Zymeworks, presented updated results from the Phase 2b HERIZON-BTC trial of zanidatamab in previously treated, HER2-amplified biliary tract cancer as an oral presentation at ASCO.

Manufacturing Operations

- Continued construction at the $700+ million 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 ready in 2024;

- Continued construction on our state-of-the-art biologics facility in Guangzhou, China, which has a current total capacity of 64,000 liters, including both single-use and stainless-steel technologies; the site continues the construction of an ADC production facility and additional biologics clinical production to be completed in 2024; 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 per year, and to be completed in 2023; once completed, qualified and approved, it is expected to increase the current small molecule manufacturing capacity in China by more than 5 times; the site also started construction of a new R&D center that will improve both clinical and manufacturing capabilities, to be completed in 2024.

Corporate Developments

- BeiGene regained full, global rights to develop, manufacture and commercialize investigational TIGIT inhibitor ociperlimab as the result of a mutual decision with Novartis to terminate the Option, Collaboration and License Agreement with Novartis pursuant to which BeiGene granted Novartis an exclusive time-based option to receive such rights in North America, Europe, and Japan, and;

- In partnership with Luye Pharma, launched BAITUOWEI® (Goserelin Microspheres for Injection) for the treatment of patients with prostate cancer requiring androgen deprivation therapy in China, which broadens our footprint in urological malignancy indications.

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Financial Summary

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

(Amounts in thousands of U.S. Dollars)

	As of	
	June 30, 2023	**December 31 2022**
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 3,527,267	$ 4,540,288
Accounts receivable, net	299,282	173,168
Inventories	321,333	282,346
Property, plant and equipment, net	1,031,938	845,946
Total assets	5,728,736	6,379,290
Liabilities and equity:		
Accounts payable	266,975	294,781
Accrued expenses and other payables	454,950	467,352
Deferred revenue	183,310	255,887
R&D cost share liability	271,291	293,960
Debt	628,478	538,117
Total liabilities	1,930,177	1,995,935
Total equity	$ 3,798,559	$ 4,383,355

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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		Six Months Ended	
	2023	2022 [1]	2023	2022 [1]
	(Unaudited)		(Unaudited)	
Revenue:				
Product revenue, net	$ 553,745	$ 304,511	$ 964,036	$ 566,084
Collaboration revenue	41,516	37,061	79,026	82,114
Total revenues	595,261	341,572	1,043,062	648,198
Expenses:				
Cost of sales - products	95,990	71,173	177,779	136,410
Research and development	422,764	378,207	831,348	768,122
Selling, general and administrative	395,034	331,403	723,533	625,976
Amortization of intangible assets	188	188	375	376
Total expenses	913,976	780,971	1,733,035	1,530,884
Loss from operations	(318,715)	(439,399)	(689,973)	(882,686)
Interest income, net	15,070	11,431	31,086	21,502
Other expense, net	(63,818)	(129,617)	(45,515)	(117,650)
Loss before income taxes	(367,463)	(557,585)	(704,402)	(978,834)
Income tax expense	13,674	8,141	25,166	22,090
Net loss	(381,137)	(565,726)	(729,568)	(1,000,924)
Net loss per share attributable to BeiGene, Ltd.:				
Basic and diluted	$ (0.28)	$ (0.42)	$ (0.54)	$ (0.75)
Weighted-average shares outstanding:				
Basic and diluted	1,360,224,377	1,336,463,02	1,357,211,308	1,334,252,648
Net loss per ADS attributable to BeiGene, Ltd.:				
Basic and diluted	$ (3.64)	$ (5.50)	$ (6.99)	$ (9.75)
Weighted-average ADSs outstanding:				
Basic and diluted	104,632,644	102,804,848	104,400,870	102,634,819

[1] The Company 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 its previously filed financial statements in the second quarter of 2022 (see "Notes to the Condensed Consolidated Financial Statements, Note 1. Description of Business, Basis of Presentation and Consolidation and Significant Accounting Policies" and "Note 2. Revision of Prior Period Financial Statements" included in our Quarterly Report on Form 10-Q for the period ended June 30, 2023, filed with the SEC).

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 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 the potential for BRUKINSA to become the BTK inhibitor of choice; the ability of BeiGene's pipeline to drive growth; the potential for BeiGene to fulfill its mission of providing innovative cancer medicines and improving treatment options for more patients around the world; the expected continued decrease in net loss through 2023; 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 captions "Key Business and Pipeline Highlights" and "Anticipated Upcoming Milestones"; the expected capacities and completion dates for the Company's manufacturing facilities under construction and the potential for such facilities to improve clinical and 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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