BeiGene Reports First Quarter 2023 Financial Results and Corporate Developments

- *Recorded first quarter product revenue of $410.3 million, increasing 56.9% over $261.6 million from the prior-year period*

- *Launched BRUKINSA® in the U.S. for adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL); global BRUKINSA product revenue totaled $211.4 million, more than doubling from first quarter 2022*

- *Continued to build on leading position in China oncology market, supported by success of tislelizumab and BRUKINSA*

BASEL, Switzerland; BEIJING; and CAMBRIDGE, Mass., May 4, 2023 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today reported financial results for the first quarter 2023, recent business highlights, and upcoming milestones.

"Our two cornerstone medicines, BRUKINSA and tislelizumab, achieved significant global growth in the first quarter as we continue to advance our pipeline of innovative therapies for patients with cancer," said John V. Oyler, Co-Founder, Chairman and CEO at BeiGene. "The strong uptake of BRUKINSA following recent global approvals in CLL speaks to the importance of a BTKi that has demonstrated superior efficacy and safety to IMBRUVICA®. We are committed to bringing our impactful medicines to more patients around the world."

"Our first-quarter results demonstrate BeiGene's progress in operational excellence and financial discipline to bring affordable and accessible medicines to more patients globally," said Julia Wang, Chief Financial Officer at BeiGene. "With product revenues continuing to grow meaningfully faster than operational expenses, BeiGene is well positioned for future growth."

First Quarter 2023 Financial Results

Revenue for the three months ended March 31, 2023, was $447.8 million, compared to $306.6 million in the same period of 2022.

- Product revenue totaled $410.3 million for the three months ended March 31, 2023, compared to $261.6 million in the same period of 2022, including:
  - Global sales of BRUKINSA of $211.4 million for the first quarter of 2023, compared to $104.3 million in the prior-year period;
  - Sales of tislelizumab in China of $114.9 million for the first quarter of 2023, compared to $87.6 million in the prior-year period; and
  - Sales of Amgen in-licensed products in China of $36.4 million for the first quarter of 2023, compared to $29.9 million in the prior-year period.
- Collaboration revenue for the three months ended March 31, 2023, was $37.5 million, resulting from partial recognition of the upfront payments from Novartis related to the tislelizumab and ociperlimab agreements, which were entered into in the first quarter and fourth quarter of 2021, respectively. This compared to $45.1 million in the prior-year period.

Cost of Product Sales for the first quarter of 2023 was $81.8 million, compared to $65.2 million in the prior-year period. Cost of sales increased primarily due to increased product sales of BRUKINSA and tislelizumab, as well as sales of XGEVA® and POBEVCY®.

Gross Margin as a percentage of global product sales for the first quarter of 2023 was 80.1%, compared to 75.1% 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 sales compared to other products in the portfolio and compared to lower-margin sales of in-licensed products.

Operating Expenses for the three months ended March 31, 2023, were $737.3 million, compared to $684.7 million in the same period of 2022.

- **R&D Expenses** for the three months ended March 31, 2023, were $408.6 million, compared to $389.9 million in the prior-year period. 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 clinical operations activities, partially offset by lower fees paid to clinical research organizations for clinical trials. Employee share-based compensation expense was $34.0 million for the first quarter of 2023, compared to $30.9 million in the prior-year period; and

- **SG&A Expenses** for the three months ended March 31, 2023, were $328.5 million, compared to $294.6 million in the prior-year period. The increase in SG&A expenses was primarily attributable to increased headcount, largely related to the expansion of our commercial teams, higher external commercial expenses, including market access and promotional activities. Employee share-based compensation expense was $41.4 million and $34.7 million for the first quarters of 2023 and 2022, respectively.

Net Loss for the quarter ended March 31, 2023, was $348.4 million, or $0.26 per share, and $3.34 per American Depositary Share (ADS), compared to $435.2 million, or $0.33 per share, and $4.25 per ADS in the same period of 2022. 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 through 2023.

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were $3.8 billion as of March 31, 2023, and $4.5 billion as of December 31, 2022.

- In the three months ended March 31, 2023, cash used in operating activities was $563.8 million, primarily due to our net loss of $348.4 million and an increase in working capital of $294.1 million due to the seasonality of receivables and compensation-related payments. These were partially offset by non-cash charges within net loss of $78.7 million. Capital expenditures were $125.6 million and cash used in financing activities was $19.9 million;

  In the three months ended March 31, 2022, cash used in operating activities was $236.6 million, primarily due to our net loss of $435.2 million, partially offset by non-cash charges within net loss of $80.9 million. Net operating assets and liabilities contributed $117.7 million of cash due to the collection of the $300 million upfront fee from Novartis for ociperlimab, partially offset by seasonality of working capital due to compensation-related payments. Capital expenditures were $45.1 million, and cash used in financing activities was $11.3 million.

Recent Business Highlights

Commercial Operations

- Product sales increased 57% in the first 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 and Bio-Thera;

- Global sales of BRUKINSA totaled $211.4 million in the first quarter, representing a 103% increase compared to the prior-year period. U.S. sales of BRUKINSA totaled $138.8 million in the first quarter, representing growth of 104% over the prior-year period, driven by the launch for adult patients with CLL/SLL. BRUKINSA adoption accelerated across all FDA-approved indications, as clinicians expanded use and the prescriber base continued to grow. BRUKINSA sales in China totaled $48.1 million, representing growth of 44% over the prior-year period, driven by increases in all approved indications; and

- Sales of tislelizumab in China totaled $114.9 million in the first quarter, representing growth of 31% compared to the prior-year period. Continued increase in new patient demand from broader reimbursement and further expansion of our salesforce efficiency and hospital listings continued to drive increased market penetration and market share for tislelizumab.

Regulatory Progress and Development Programs

BRUKINSA® (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, 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 4,900 subjects enrolled to-date in 29 countries and regions.*

- Submitted a supplemental New Drug Application (sNDA) to the U.S. FDA based on results from a final progression-free survival analysis of the Phase 3 ALPINE trial in adult patients with R/R CLL;
- Received approval in Australia for the treatment of adult patients with CLL/SLL;
- Received acceptance in the European Union for sNDA submissions for R/R follicular lymphoma (FL) and PFS superiority in R/R CLL;
- Submitted sNDAs for R/R FL in Switzerland, the United Kingdom and Canada, under the ACCESS consortium; and
- Expanded BRUKINSA's registration program globally, including potential launches in more than 30 markets in 2023.

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 12,100 subjects enrolled to date in 31 countries and regions.*

- Presented results from the RATIONALE-302 (NCT03430843), RATIONALE-304 (NCT03663205), RATIONALE-306 (NCT03783442), RATIONALE-307 (NCT03594747) at the 2023 American Association for Cancer Research (AACR) meeting;
- Announced positive Phase 3 trial in advanced gastric or gastroesophageal junction adenocarcinoma; and
- U.S. FDA pre-approval manufacturing inspections for tislelizumab biologics license application (BLA) scheduled for Q2.

Ociperlimab (BGB-A1217)*, an investigational anti-TIGIT monoclonal antibody with competent Fc function. The global ociperlimab development program includes 20 countries and regions, and more than 1,700 subjects have been enrolled.*

- Completed enrollment in a Phase 2 trial (NCT05014815) in combination with tislelizumab and chemotherapy in first-line non-small cell lung cancer (NSCLC).

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 seven countries and regions, and more than 430 subjects have been enrolled.*

- Continued to advance development with potentially registration-enabling Phase 2 studies in R/R mantle cell lymphoma (MCL) (NCT05471843) and R/R CLL/SLL (NCT05479994).

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

- Completed enrollment in a Phase 1 dose-escalation trial in combination with tislelizumab in solid tumors (NCT04215978).

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 anti-TIM-3 antibody, in combination with tislelizumab in patients with head and neck squamous cell carcinoma, NSCLC and renal cell carcinoma;
- 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, mimetic as monotherapy or in combination with paclitaxel in advanced solid tumors; presented pre-clinical study results at AACR Annual Meeting 2023;
- BGB-10188: an investigational PI3Kδ inhibitor as monotherapy or in combination with BRUKINSA in hematologic malignancies, or in combination with tislelizumab in solid tumors; and
- BGB-23339: a potent, allosteric investigational tyrosine kinase 2 inhibitor.

Collaboration Programs

- In collaboration with SpringWorks Therapeutics, presented Phase 1b clinical data for lifirafenib (BGB-283), an investigational B-RAF inhibitor, with SpringWorks' MEK inhibitor, mirdametinib, in patients with advanced or refractory solid tumors with RAS mutations, RAF mutations and other MAPK pathway aberrations at AACR;
- In collaboration with MapKure and SpringWorks, presented Phase 1a/b clinical data for brimarafenib (BGB-3245), an investigational, selective RAF dimer inhibitor, in adult patients with advanced or refractory solid tumors harboring MAPK pathway mutations at AACR;
- In collaboration with Leads Biolabs, initiated enrollment for Phase 2 clinical trial of LBL-007, a novel investigational antibody targeting the LAG-3 pathway, in combination with tislelizumab and bevacizumab plus capecitabine in unresectable or metastatic CRC (NCT05609370); and
- Also in collaboration with Leads Biolabs, initiated patient dosing of LBL-007 in combination with tislelizumab, in umbrella studies comparing different tislelizumab combination regimens, including with BGB-A445 and ociperlimab (NCT05635708, NCT05577702).

Manufacturing Operations

- The final piece of structural steel was placed for the company's U.S. flagship manufacturing and clinical R&D facility under construction 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;
- Continued construction on our state-of-the-art biologics facility in Guangzhou, China, which has a current total capacity of 54,000 liters, with an expansion of 10,000 liters expected in the second quarter of 2023;

- Started construction of an antibody drug conjugate (ADC) production facility and additional biologics clinical production building in Guangzhou, to be completed in 2024; and started construction of a new R&D center in Suzhou, China, that will improve both clinical and manufacturing capabilities, to be completed in 2025; 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, it is expected to increase the total small molecule manufacturing capacity in China by up to 10 times current capacity.

Corporate Developments

- Announced the formal opening of a corporate office in Sao Paulo, Brazil, as part of broader expansion plans in Latin America.

Expected Milestones

BRUKINSA

- Continue to support U.S. FDA and European Medicines Agency (EMA) review of sNDA for PFS superiority in R/R CLL;
- Continue to support National Medical Products Administration 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 review of sNDA for CLL, with decision expected in 2023;
- Continue to expand BRUKINSA's registration program globally in new geographies and indications; and
- Presentation of results from the first interim analysis of a Phase 1 study of zanubrutinib plus lenalidomide in patients with R/R diffuse large B-cell lymphoma at the ASCO 2023 Annual Meeting, as well as abstract for updated analysis of the ROSEWOOD study of zanubrutinib plus obinutuzumab versus obinutuzumab in patients with relapsed/refractory follicular lymphoma.

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 Ministry of Food and Drug Safety review of BLA for tislelizumab in second-line ESCC; and
  - Brazil's Anvisa review of BLA for tislelizumab in first- and second-line NSCLC and second-line ESCC;
- In collaboration with Novartis, continue to support review of marketing applications, including:
  - Ongoing U.S. FDA review of the BLA submission in second-line ESCC, with a decision expected in 2023;
  - EMA review of marketing authorization applications for tislelizumab in first- and second-line NSCLC and second-line ESCC, with a decision expected in 2023;

  - Medicines and Healthcare products Regulatory Agency 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; and
  - Submit BLA to Japan's Pharmaceutical and Medical Devices Agency in 2023 for first- and second-line ESCC.
- Announce final analysis data from pivotal trials in extensive-stage small cell lung cancer in 2023; and
- Two abstracts for additional analyses of RATIONALE 301 accepted for poster presentation at 2023 ASCO Annual Meeting.

BGB-11417 (BCL-2 inhibitor)

- Initiate global pivotal trial in first-line CLL in combination with BRUKINSA in the second half of 2023;
- Announce readouts from ongoing studies; and
- Abstract for a Phase 1 study evaluating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity BGB-11417 in adult patients with mature B-cell malignancies accepted for poster presentation at 2023 ASCO Annual Meeting.

Ociperlimab (anti-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 hepatocellular carcinoma (NCT04948697); and
  - For first-line NSCLC (NCT05014815).
- Complete enrollment in the Phase 3 AdvanTIG-302 trial in first-line NSCLC in 2023; and
- Abstract for Phase 1b AdvanTIG-105 study accepted for poster presentation at ASCO 2023 Annual Meeting.

BGB-16673 (BTK CDAC)

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

BGB-A445 (anti-OX 40)

- Initial data readout for Phase 1 study in solid tumors (NCT04215978) in 2023; and
- Abstract for a Phase 1 study of the OX40 agonist, BGB-A445, with or without tislelizumab in patients with advanced solid tumors accepted for poster presentation at the 2023 ASCO Annual Meeting.

BGB-15025 (HPK 1)

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

Collaboration Programs

- Abstract for updated results from a Phase 1b/2 study of zanidatamab, a HER2-targeted bispecific antibody, in combination with docetaxel as first-line therapy for patients with advanced HER2-positive breast cancer accepted for

poster presentation at 2023 ASCO Annual Meeting, as well as an abstract for the pivotal Phase 2b HERIZON-BTC-01 study with zanidatamab in previously treated HER2 amplified Biliary Tract Cancer accepted for oral presentation.

COVID-19 Impact and Response

We are continuing to monitor the impact of the effects of the COVID-19 pandemic on our business. It is possible that the COVID-19 pandemic continues to have a negative impact on our operations, including commercial sales, regulatory interactions, inspections, filings, manufacturing, and clinical trial recruitment, participation, and data readouts. 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	
	March 31, 2023	December 31, 2022
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 3,837,823	$ 4,540,288
Accounts receivable, net	309,628	173,168
Inventories	296,995	282,346
Property and equipment, net	925,404	845,946
Total assets	5,956,775	6,379,290
Liabilities and equity:		
Accounts payable	241,360	294,781
Accrued expenses and other payables	417,922	467,352
Deferred revenue	222,822	255,887
R&D cost share liability	276,562	293,960
Debt	488,106	538,117
Total liabilities	1,799,469	1,995,935
Total equity	$ 4,157,306	$ 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 March 31,	
	2023	2022 [1]
	(Unaudited)	
Revenue:		
Product revenue, net	$ 410,291	$ 261,573
Collaboration revenue	37,510	45,053
Total revenues	447,801	306,626
Expenses:		
Cost of sales - products	81,789	65,237
Research and development	408,584	389,915
Selling, general and administrative	328,499	294,573
Amortization of intangible assets	187	188
Total expenses	819,059	749,913
Loss from operations	(371,258)	(443,287)
Interest income (expense), net	16,016	10,071
Other (loss) income, net	18,303	11,967
Loss before income taxes	(336,939)	(421,249)
Income tax expense	11,492	13,949
Net loss	(348,431)	(435,198)
Net loss per share attributable to BeiGene, Ltd.:		
Basic and diluted	$ (0.26)	$ (0.33)
Weighted-average shares outstanding:		
Basic and diluted	1,354,164,760	1,332,017,262
Net loss per ADS attributable to BeiGene, Ltd.:		
Basic and diluted	$ (3.34)	$ (4.25)
Weighted-average ADSs outstanding:		
Basic and diluted	104,166,520	102,462,866

[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 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 March 31, 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 9,400 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 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 expected future growth of BeiGene, including expansion in Latin America; the potential for BRUKINSA to provide clinical benefit to patients including superior efficacy and safety compared with the comparator drug; the future success of BeiGene's commercialization efforts and product revenue growth; the expected decrease in BeiGene's future operational expenses; 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; 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; and those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent annual report on Form 10-K, 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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