BeiGene Reports Second Quarter 2022 Financial Results

- *Recorded product revenue of $304.5 million for the second quarter, representing a 120% increase from $138.6 million in the prior year period*

- *BRUKINSA product revenue increased 203% globally versus the second quarter of 2021, and 23% sequentially compared to the first quarter of 2022, led by growth in U.S. and China*

- *New global clinical data support FDA and EMA filings under review for BRUKINSA and tislelizumab*

CAMBRIDGE, Mass., BASEL, Switzerland and BEIJING, China, August 4, 2022 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company developing and commercializing innovative and affordable oncology medicines to improve treatment outcomes and access for far more patients worldwide, today reported financial results for the second quarter of 2022, recent business highlights, and anticipated upcoming milestones.

"We made significant progress in our mission to reach far more cancer patients with innovative and affordable medicines, with growth in product revenues across our portfolio, driven primarily by our internally developed medicines, BRUKINSA and tislelizumab. We have now expanded our approvals to more than 50 markets globally, and BRUKINSA global revenue more than tripled on a year-over-year basis," said John V. Oyler, Co-Founder, Chairman and Chief Executive Officer of BeiGene. "We continue to unlock opportunity driven by our research and development engine and, during the second half of this year, expect to share final analysis data for our global Phase 3 ALPINE trial of BRUKINSA, including progression-free survival in chronic lymphocytic leukemia as well as topline data for tislelizumab as a first-line treatment for patients with unresectable hepatocellular cancer."

"BeiGene is well positioned for growth with momentum across our commercial portfolio and geographies and a strong capital position. We are continuing to execute with discipline and realize the benefits of our strategic investments in research and commercial capabilities," said Julia Wang, Chief Financial Officer, BeiGene.

Second Quarter 2022 Financial Results

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were $5.7 billion as of June 30, 2022 and $6.6 billion as of December 31, 2021.

- In the three months ended June 30, 2022, cash used in operating activities was $380.0 million, primarily due to our net loss of $571.4 million, offset by a decrease in our net operating assets and liabilities of $96.3 million, and by non-cash charges of $95.2 million. Net loss for the three months ended June 30, 2022 includes $129.6 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. Capital expenditures were $50.3 million and cash used in financing activities was $17.6 million. In addition, the impact of foreign currency deposits being translated into the U.S. dollar negatively impacted ending cash by $80.2 million in the three months ended June 30, 2022 compared to a positive impact of $9.3 million in the prior year period.

Revenue for the three months ended June 30, 2022 was $341.6 million, compared to $150.0 million in the same period of 2021.

- Product revenue totaled $304.5 million for the three months ended June 30, 2022, compared to $138.6 million in the same period of 2021, including:

  – Global sales of BRUKINSA of $128.7 million for the second quarter of 2022, compared to $42.4 million in the prior year period;

  – Sales of tislelizumab in China of $104.9 million for the second quarter of 2022, compared to $74.9 million in the prior year period;

  - Sales of Amgen in-licensed products in China of $29.5 million for the second quarter of 2022, compared to $3.3 million in the prior year period. Prior year period sales do not include sales of BLINCYTO® and KYPROLIS®, which were launched in China in August 2021 and January 2022, respectively; and

  - Sales of BMS in-licensed products in China of $23.4 million for the second quarter of 2022, compared to $13.4 million in the prior year period.

- Collaboration revenue for the three months ended June 30, 2022 was $37.1 million, resulting from partial recognition of the upfront payments from Novartis of $650.0 million related to the tislelizumab agreement and $300.0 million related to the ociperlimab agreement, which were entered into in the first quarter and fourth quarter of 2021, respectively. Collaboration revenue for the three months ended June 30, 2021 was $11.4 million, resulting from the partial recognition of revenue related to the tislelizumab agreement.

Expenses for the three months ended June 30, 2022 were $781.0 million, compared to $624.8 million in the same period of 2021.

- **Cost of Sales** for the three months ended June 30, 2022 were $71.2 million, compared to $36.3 million in the same period of 2021. Cost of sales increased primarily due to increased product sales of tislelizumab and BRUKINSA, as well as BLINCYTO, which commenced in August 2021, and KYPROLIS and POBEVCY, which commenced in January 2022.

- **R&D Expenses** for the three months ended June 30, 2022 were $378.2 million, compared to $356.1 million in the same period of 2021. 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 decreased expense related to upfront fees for in-process R&D. Upfront fees related to in-process R&D for in-licensed assets totaled nil and $45.0 million in the second quarters of 2022 and 2021, respectively. Employee share-based compensation expense also contributed to the overall increase in R&D expenses and was $37.1 million for the three months ended June 30, 2022, compared to $30.2 million for the same period of 2021.

- **SG&A Expenses** for the three months ended June 30, 2022 were $331.4 million, compared to $232.3 million in the same period of 2021. The increase in SG&A expenses was primarily attributable to increased headcount, largely related to the expansion of our commercial teams, higher professional service fees and higher external commercial expenses, including selling and marketing, market access studies and promotional activities. The overall increase in SG&A expenses was also attributable to higher SG&A-related share-based compensation expense, which was $44.2 million and $34.6 million for the second quarters of 2022 and 2021, respectively.

- **Operating Loss** for the three months ended June 30, 2022 decreased by $35.4 million, or 7.5% to $439.4 million, compared to $474.8 million in the same period of 2021. The decrease in operating loss for the quarter was driven by increased gross profit on product sales, which exceeded the growth in operating expenses.

- **Net Loss** for the quarter ended June 30, 2022 was $571.4 million, or $0.43 per share, and $5.56 per American Depositary Share (ADS), compared to $480.3 million, or $0.40 per share, and $5.23 per ADS in the same period of 2021. Net loss for the quarter was negatively impacted by other non-operating expenses of $129.6 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.

Recent Business Highlights

Commercial Operations

- Product sales increased 120% in the second quarter of 2022 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;

- Global sales of BRUKINSA totaled $128.7 million in the second quarter, representing a 203% increase compared to the prior year period. U.S. sales of BRUKINSA totaled $88.4 million in the second quarter, representing growth of 456% compared to the prior year period, as the U.S. prescribing base continued to grow and as clinician use increased within approved indications — mantle cell lymphoma (MCL), Waldenström's macroglobulinemia (WM) and marginal zone lymphoma (MZL). BRUKINSA sales in China totaled $36.7 million in the second quarter, representing growth of 39% compared to the prior year period, driven by a continued increase in all approved indications; and
- Sales of tislelizumab in China totaled $104.9 million in the second quarter, representing a 40% increase compared to the prior year period. In the second quarter, we saw increased market penetration and market share for tislelizumab across nine approved indications, resulting from new patient demand from broader reimbursement in additional National Reimbursement Drug List.

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 50 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 4,500 subjects enrolled to-date in more than 25 countries and regions.*

- Received approval in Mexico for BRUKINSA for the treatment of adult patients with previously treated MCL;
- Received U.S. FDA fast track designation to investigate zanubrutinib in combination with obinutuzumab, for the treatment of adults with relapsed or refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy;
- Received acceptance by Health Canada for supplemental new drug submission (sNDS) for zanubrutinib in chronic lymphocytic leukemia (CLL);
- Presented primary analysis of the global Phase 2 ROSEWOOD trial (NCT03332017) of zanubrutinib plus obinutuzumab versus obinutuzumab monotherapy in patients with R/R FL in an oral presentation at the European Hematology Association (EHA) 2022 Congress as well as at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. The ROSEWOOD trial met its primary endpoints of overall response rate (ORR) and was generally well-tolerated, with safety results consistent with previous studies of both medicines; and
- Presented long-term follow-up safety and efficacy results from the Phase 3 ASPEN trial (NCT03053440) of zanubrutinib versus ibrutinib in patients with WM at the 2022 EHA Congress and ASCO Annual Meetings, which showed that, at a median follow up of 43 months, zanubrutinib continued to demonstrate clinically meaningful efficacy and a tolerable safety profile in patients with WM.

Tislelizumab*, a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages; approved in China in nine indications and under development for additional approvals globally. The global tislelizumab clinical development program includes more than 11,000 subjects enrolled to-date in 30 countries and regions.*

- Received approval from the China National Medical Products Administration (NMPA) for tislelizumab in combination with chemotherapy as a first-line (1L) treatment for patients with recurrent or metastatic nasopharyngeal cancer (NPC);
- Announced acceptance by the Center for Drug Evaluation (CDE) of the NMPA for a supplemental biologics application (sBLA) for tislelizumab in combination with chemotherapy as a 1L treatment for patients with advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1;
- Notification of successful dossier validated from Australia's Therapeutic Goods Administration (TGA) for the new drug application of tislelizumab in 1L and second-line (2L) non-small cell lung cancer (NSCLC) and 2L esophageal squamous cell carcinoma (ESCC);

- In collaboration with Novartis, the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) has validated the tislelizumab submission for review as a treatment for 1L and 2L NSCLC and 2L ESCC in Great Britain;
- Presented a late-breaking oral presentation at the 2022 European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer on new data from RATIONALE 306 (NCT03783442), a global Phase 3 trial which showed overall survival benefit for tislelizumab plus chemotherapy versus chemotherapy alone in 1L advanced or metastatic ESCC; and
- Presented updated results in an oral plenary session from the global Phase 3 RATIONALE 309 trial (NCT03924986) of tislelizumab in 1L patients with NPC, and in a poster session reviewed clinical outcomes associated with tislelizumab in patients with advanced hepatocellular carcinoma (HCC) who have previously been treated with sorafenib or lenvatinib in RATIONALE 208 (NCT03419897) at the 2022 ASCO Annual Meeting.

Early-Stage Programs

- Presented two posters from dose escalation studies of BGB-11417 (NCT04277637 and NCT04771130), a highly selective investigational BCL2 inhibitor in CLL, non-Hodgkin's lymphoma and acute myeloid leukemia (AML) at the EHA 2022 Congress;
- Initiated tumor-specific dose expansion cohorts in Phase 1 trial (NCT04215978) in patients with solid tumors of BGB-A445, an investigational non-ligand competing OX40 monoclonal antibody, as monotherapy;
- Initiated patient dosing in the Phase 1 trial (NCT05381909) in patients with advanced or metastatic solid tumors for BGB-24714, an investigational second mitochondrial-derived activator of caspase (SMAC) mimetic;
- Continued to advance our early-stage clinical pipeline of internally developed product candidates at dose escalation stage, including:
  - BGB-15025: an investigational hematopoietic progenitor kinase 1 (HPK1) inhibitor as monotherapy or in combination with tislelizumab in solid tumors;
  - BGB-10188: an investigational PI3Kδ 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.

Amgen Milestones

- In collaboration with Amgen, launched BLINCYTO (blinatumomab) for injection for the treatment of pediatric patients with R/R CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL); and
- Entered into a clinical trial collaboration and supply agreement with Amgen, in which Amgen provides KYPROLIS for a combination study conducted by BeiGene of BGB-11417 plus dexamethasone and carfilzomib in R/R multiple myeloma.

Zymeworks Milestones

- In collaboration with Zymeworks, presented preliminary results from two Phase 1b/2 studies at the ASCO 2022 Annual Meeting evaluating zanidatamab:
  - In combination with docetaxel as a 1L therapy for patients with advanced HER2-positive breast cancer; and
  - In combination with chemotherapy and tislelizumab as a 1L therapy for patients with HER-2 positive gastric/gastroesophageal junction adenocarcinoma.

Manufacturing Operations

- Construction has begun on the U.S. flagship commercial-stage manufacturing and clinical R&D campus at the Princeton West Innovation Campus in Hopewell, N.J. The property has more than one million square feet of developable real estate for potential future expansion;
- Continued construction on our new small molecule manufacturing campus in Suzhou, China. Phase 1 of construction is expected to bring more than 52,000 square meters and expand production capacity to 600 million tablets/capsules and 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 a total of ten times capacity; and
- Continued construction on our state-of-the-art biologics facility in Guangzhou, China, which currently is approved for 8,000 liters of biologics capacity, with an additional Phase of construction to bring total capacity to 64,000 liters expected to be completed and GMP-ready by the end of 2022.

Corporate Developments

- Announced a strategic research collaboration with InnoRNA to jointly discover mRNA therapies, under which we will hold exclusive global development and commercialization rights; and
- Appointed Chan Lee as General Counsel. Mr. Lee will serve on our Executive Committee and report directly to John V. Oyler.

Expected Milestones

BRUKINSA

- Continue to support ongoing FDA review of the sNDA for CLL/small lymphocytic lymphoma, which has a PDUFA target action date of January 2023;
- Continue to support the European Medicines Agency (EMA) review of new indication applications for CLL and MZL;
- Continue to support Health Canada review of sNDA for CLL;
- Announce final analysis data for the global Phase 3 ALPINE trial (NCT03734016) including progression-free survival in 2022; and
- Continue to expand BRUKINSA's registration program globally in new geographies and indications, including potential launches in 2022 in more than 10 markets.

Tislelizumab

- Continue to support NMPA review of BLA application for tislelizumab in combination with chemotherapy as a 1L treatment for patients with advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1;
- Continue to support Australia's TGA review of NDA for tislelizumab in 1L/2L NSCLC and 2L ESCC;
- In collaboration with Novartis, continue to support UK MHRA review of tislelizumab for treatment of 1L/2L NSCLC and 2L ESCC in Great Britain;
- In collaboration with Novartis, continue to support the EMA review of marketing authorization applications for tislelizumab in NSCLC and 2L ESCC;
- In collaboration with Novartis, continue to support the ongoing FDA review of the BLA submission in 2L ESCC to support scheduling the required inspections as soon as possible. In the FDA's general advice letter communicating the deferral of action, the FDA cited only the inability to complete inspections due to restrictions on travel as the reason

for the deferral and did not provide a new anticipated action date as they continue to monitor the public health situation and travel restrictions;

- Continue to support planned regulatory submissions by Novartis for 1L gastric cancer, 1L and localized ESCC, and 1L HCC in the U.S. in 2023. No additional submissions planned in the U.S. in 2022;
- Announce topline results from the global Phase 3 clinical trial (NCT03412773) of tislelizumab as a 1L treatment for patients with HCC in Q3 2022.
- Present clinical data at 2022 World Conference on Lung Cancer including final analysis of the global, Phase 3 RATIONALE 303 trial (NCT03358875) with tislelizumab monotherapy compared to chemotherapy in previously treated advanced NSCLC and Phase 1 data on tislelizumab in combination with ociperlimab in metastatic NSCLC (NCT04047862); with sitravatinib in PD-L1+, locally advanced/metastatic, non-squamous NSCLC (NCT03666143); and with sitravatinib in PD-L1+, locally advanced/metastatic, squamous NSCLC (NCT03666143); and

Ociperlimab

- Initiate additional pivotal clinical trials in 2022; and
- Announce data from Phase 1 trial (NCT04047862) cohorts in various solid tumor types in 2022.

BGB-11417 (BCL-2)

- Initiate pivotal trials in 2022; and
- Present Phase 1 clinical data for non-Hodgkin's lymphoma, CLL, AML and multiple myeloma (MM) (NCT04883957, NCT04277637, NCT04771130, and NCT04973605) at a medical congress in late 2022.

Early Stage 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 and surzebiclimab (TIM3) in 2022.

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	
	June 30, 2022	December 31, 2021
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 5,707,963	$ 6,624,849
Accounts receivable, net	172,259	483,113
Property and equipment, net	633,100	587,605
Total assets	7,378,207	8,645,949
Liabilities and equity:		
Accounts payable	234,355	262,400
Accrued expenses and other payables	454,183	558,055
Deferred revenue	330,966	407,703
R&D cost share liability	344,779	390,362
Debt	565,936	629,678
Total liabilities	2,075,663	2,402,962
Total equity	$ 5,302,544	$ 6,242,987

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Revenue:				
Product revenue, net	$ 304,511	$ 138,624	$ 566,084	$ 244,741
Collaboration revenue	37,061	11,368	82,114	511,123
Total revenues	341,572	149,992	648,198	755,864
Expenses:				
Cost of sales - products	71,173	36,263	136,410	68,948
Research and development	378,207	356,091	768,122	676,817
Selling, general and administrative	331,403	232,289	625,976	414,395
Amortization of intangible assets	188	187	376	375
Total expenses	780,971	624,830	1,530,884	1,160,535
Loss from operations	(439,399)	(474,838)	(882,686)	(404,671)
Interest income (expense), net	11,431	(4,866)	21,502	(9,045)
Other loss, net	(129,617)	(867)	(117,650)	(4,990)
Loss before income taxes	(557,585)	(480,571)	(978,834)	(418,706)
Income tax expense (benefit)	13,864	(230)	26,889	(4,860)
Net loss	(571,449)	(480,341)	(1,005,723)	(413,846)
Net loss per share attributable to BeiGene, Ltd.:				
Basic and diluted	$ (0.43)	$ (0.40)	$ (0.75)	$ (0.35)
Weighted-average shares outstanding:				
Basic and diluted	1,336,463,026	1,194,071,476	1,334,252,648	1,191,521,766
Net loss per ADS attributable to BeiGene, Ltd.				
Basic and diluted	$ (5.56)	$ (5.23)	$ (9.80)	$ (4.52)
Weighted-average ADSs outstanding:				
Basic and diluted	102,804,848	91,851,652	102,634,819	91,655,520

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 8,500 colleagues spans five continents, with administrative offices in Beijing, China; Cambridge, Mass.; and Basel, Switzerland. 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 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.

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