

BeiGene Reports Third Quarter 2022 Financial Results

- Recorded product revenue of \$349.5 million for the third quarter, representing an 82% increase from \$192.5 million in the prior-year period
- BRUKINSA product revenue totaled \$155.5 million, increasing 136% globally versus the third quarter of 2021, led by growth in the U.S.
 - Tislelizumab revenue in China reached \$128.2 million, a 67% increase over the prior year period
- BRUKINSA achieved superior Progression-Free Survival vs. IMBRUVICA in final analysis of Phase 3 ALPINE trial

CAMBRIDGE, Mass., BASEL, Switzerland, and BEIJING, November 9, 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 third quarter of 2022, recent business highlights, and anticipated upcoming milestones.

“BeiGene generated strong product revenue in the third quarter, led by growth of our internally developed cornerstone assets, BRUKINSA[®] and tislelizumab, and BRUKINSA has now been approved in more than 55 markets around the world,” said John V. Oyler, Co-Founder, Chairman and Chief Executive Officer of BeiGene. “We are delighted with the recently reported positive topline results from the final progression-free survival analysis of BRUKINSA compared to IMBRUVICA[®], which supports our confidence in BRUKINSA as a potential new treatment that can provide hope for patients and families with CLL. We look forward to sharing the full data with the medical and patient communities, to important milestones in the coming months and to a strong finish for 2022.”

“Our third quarter results underscore our commercial capabilities and the commitment of our more than 9,000 colleagues across 29 countries and regions to operating with excellence,” said Julia Wang, Chief Financial Officer, BeiGene. “Following the close of the third quarter, our total product revenue this year has now exceeded \$1 billion, an exciting milestone for the company. BeiGene is well positioned to leverage its financial strength and multiple upcoming catalysts for long-term growth.”

Third Quarter 2022 Financial Results

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were \$5.1 billion as of September 30, 2022, and \$6.6 billion as of December 31, 2021.

- In the three months ended September 30, 2022, cash used in operating activities was \$561.9 million, primarily due to our net loss of \$557.6 million and an increase in our net operating assets and liabilities of \$88.0 million, offset by non-cash charges of \$83.7 million. Net loss for the three months ended September 30, 2022, includes \$125.6 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 \$108.7 million and cash provided by financing activities was \$120.2 million. In addition, the impact of foreign currency deposits being translated into the U.S. dollar negatively impacted ending cash by \$62.7 million in the three months ended September 30, 2022.

Revenue for the three months ended September 30, 2022, was \$387.6 million, compared to \$206.4 million in the same period of 2021.

- Product revenue totaled \$349.5 million for the three months ended September 30, 2022, compared to \$192.5 million in the same period of 2021, including:
 - Global sales of BRUKINSA of \$155.5 million for the third quarter of 2022, compared to \$65.8 million in the prior year period;
 - Sales of tislelizumab in China of \$128.2 million for the third quarter of 2022, compared to \$77.0 million in the prior year period;

- Sales of Amgen in-licensed products in China of \$27.5 million for the third quarter of 2022, compared to \$20.8 million in the prior-year period. Prior-year period sales do not include sales of KYPROLIS[®], which was launched in China in January 2022; and
- Sales of BMS in-licensed products in China of \$22.4 million for the third quarter of 2022, compared to \$26.0 million in the prior year period.
- Collaboration revenue for the three months ended September 30, 2022, was \$38.1 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 option agreement, which were entered into in the first quarter and fourth quarter of 2021, respectively. Collaboration revenue for the three months ended September 30, 2021, was \$14.0 million, resulting from the partial recognition of revenue related to the tislelizumab agreement.

Expenses for the three months ended September 30, 2022, were \$826.0 million, compared to \$668.8 million in the same period of 2021.

- **Cost of Sales** for the three months ended September 30, 2022, were \$76.5 million, compared to \$47.4 million in the same period of 2021. Cost of sales increased primarily due to increased product sales of BRUKINSA and tislelizumab, 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 September 30, 2022, were \$426.4 million, compared to \$351.9 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, as well as increased upfront fees for in-process R&D. Upfront fees related to in-process R&D for in-licensed assets totaled \$20.0 million and nil in the third quarters of 2022 and 2021, respectively. Employee share-based compensation expense also contributed to the overall increase in R&D expenses and was \$36.4 million for the three months ended September 30, 2022, compared to \$31.7 million for the same period of 2021.
- **SG&A Expenses** for the three months ended September 30, 2022, were \$322.9 million, compared to \$269.2 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 employee share-based compensation expense, which was \$41.8 million and \$35.4 million for the third quarters of 2022 and 2021, respectively.
- **Operating Loss** for the three months ended September 30, 2022, decreased by \$24.0 million, or 5.2%, to \$438.4 million, compared to \$462.3 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 September 30, 2022, was \$557.6 million, or \$0.41 per share, and \$5.39 per American Depositary Share (ADS), compared to \$438.1 million, or \$0.36 per share, and \$4.72 per ADS in the same period of 2021. Net loss for the quarter was negatively impacted by other non-operating expenses of \$125.6 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 82% in the third 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 and Bio-Thera;

- Global sales of BRUKINSA totaled \$155.5 million in the third quarter, representing a 136% increase compared to the prior-year period. U.S. sales of BRUKINSA totaled \$108.1 million in the third quarter, representing growth of 221% 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 \$39.5 million in the third quarter, representing growth of 23% compared to the prior-year period, driven by a continued increase in all approved indications, for a leading position in the China BTK market;
- Sales of tislelizumab in China totaled \$128.2 million in the third quarter, representing a 67% increase compared to the prior year period. In the third quarter, additional indications approved this year resulted in higher market penetration and market share for tislelizumab, as well as higher new patient demand from broader reimbursement in the National Reimbursement Drug List; and
- The National Institute for Health and Care Excellence (NICE) issued a final appraisal document recommending BRUKINSA for the treatment of WM in adults who have had at least one treatment, only if bendamustine plus rituximab is also suitable, marking the first and only treatment for WM to be recommended by NICE for routine use in England and Wales.

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 58 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 4,700 subjects enrolled to-date in more than 25 countries and regions.

- Announced that BRUKINSA achieved superior Progression-Free Survival (PFS) versus ibrutinib in a final analysis of the Phase 3 ALPINE trial, as assessed by an independent review committee (IRC) and investigator;
- Received European Commission approval for BRUKINSA for the treatment of MZL, making BRUKINSA the first and only BTK inhibitor for MZL approved in the European Union;
- Received positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending approval of BRUKINSA for the treatment of adults with chronic lymphocytic leukemia (CLL); and
- Expanded BRUKINSA’s registration program globally in new geographies and indications, including launches in 10 additional markets year-to-date.

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 11,500 subjects enrolled to-date in 30 countries and regions.

Highlights include:

- 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 first-line (1L) treatment in patients with unresectable locally advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC);
- A new drug application of tislelizumab in 1L and second-line (2L) non-small cell lung cancer (NSCLC) and 2L esophageal cancer is under review by MedSafe in New Zealand;
- A new drug application of tislelizumab in 2L esophageal cancer is under review by the South Korea Ministry of Food and Safety (MFDS);
- Announced that the global Phase 3 RATIONALE 301 trial with tislelizumab met its primary endpoint of non-inferior Overall Survival (OS) versus sorafenib as a 1L treatment in adult patients with unresectable hepatocellular carcinoma

(HCC). These data were accepted as a late-breaking abstract and presented in an oral session at the European Society for Medical Oncology Congress 2022 (ESMO 2022);

- Shared a poster demonstrating a consistent response for tislelizumab in RATIONALE 303 across pre-specified subgroups in a Phase 3 trial of 2L NSCLC at ESMO 2022; and
- Presented 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.

Ociprelimab (BGB-A1217), an investigational anti-TIGIT monoclonal antibody with competent Fc function. The global ociprelimab development program includes more than 25 countries and regions, and more than 1,500 subjects have been enrolled.

- Presented data from Phase 1 trial (NCT04047862) in combination with tislelizumab in PD-L1 expressing NSCLC at the 2022 World Conference on Lung Cancer (WCLC); and
- Presented additional data from Phase 1 cohorts in combination with tislelizumab and chemotherapy in NSCLC at ESMO 2022.

BGB-11417, an investigational highly selective and highly potent inhibitor of BCL-2, being developed as monotherapy or in combination with zanubrutinib. The global BGB-11417 development program includes more than 10 countries and regions, and more than 300 subjects have been enrolled.

- Initiated patient dosing in Phase 2 study (NCT05471843) to evaluate BCL-2 inhibitor BGB-11417 in patients with relapsed or refractory mantle cell lymphoma.
- Initiated patient dosing in BGB-11417-202 study, a single-arm phase 2 study to evaluate BGB-11417 in patients with RR CLL/SLL, conducted in China.

Early-Stage Programs

- Initiated patient dosing in the Phase 1 trial (NCT05494762) of 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);
- Initiated enrollment of surzebiclimab (BGB-A425) an anti-TIM3 antibody in combination with tislelizumab in tumor specific cohorts of NSCLC and head and neck squamous cell carcinoma (HNSCC) (NCT03744468); and
- Continued to advance our early-stage clinical pipeline of internally developed product candidates at dose escalation stage, including:
 - BGB-A445: an investigational non-ligand competing OX40 monoclonal antibody, as monotherapy in tumor specific cohorts of NSCLC and HNSCC or in combination with tislelizumab in advanced solid tumors;
 - BGB-15025: an investigational, first-in-class hematopoietic progenitor kinase 1 (HPK1) inhibitor as monotherapy or in combination with tislelizumab in solid tumors;
 - BGB-16673: an investigational Chimeric Degradation Activating Compound (CDAC), targeting BTK protein degradation as monotherapy in B cell malignancies;
 - BGB-24714: an investigational Second Mitochondrial-derived Activator of Caspase, or SMAC, mimetic as monotherapy or in combination with paclitaxel in advanced solid tumors;
 - BGB-10188: an investigational PI3K δ inhibitor as monotherapy or in combination with BRUKINSA in hematology malignancies, or in combination with tislelizumab in solid tumors; and

- BGB-23339: a potent, allosteric investigational tyrosine kinase 2 (TYK2) inhibitor.

Collaboration Programs

- In collaboration with Nanjing Leads Biolabs, initiated patient dosing in the BeiGene-sponsored 900-102 clinical trial of LAG3 inhibitor LBL-007 in combination with tislelizumab in advanced solid tumors (NCT03744468).

Manufacturing Operations

- Construction continues 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 16,000 liters of biologics capacity, with an additional phase of construction to bring total capacity to 54,000 liters expected to be completed and GMP-ready by the end of 2022 and an additional 10,000 liters in the second quarter of 2023.

Corporate Developments

- Entered into a strategic alliance with Ontada[®], a McKesson business with leading provider technology and actionable real-world research, education, and evidence in oncology, to improve U.S. community oncology care through the development of real-world evidence (RWE) data, tools, and insights to help increase access to affordable, cutting-edge therapies.

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) and European Commission for the approval of new indication applications for CLL;
- Continue to support Health Canada review of sNDA for CLL;
- Continue to support NMPA review of sNDA for 1L CLL/SLL in China;
- Continue to support the review of MHRA and Swissmedic for new indication application for MZL and CLL;
- Present final analysis data for the global Phase 3 ALPINE trial (NCT03734016) including progression-free survival at an upcoming medical congress; and
- Present key data from BRUKINSA clinical development programs at 64th American Hematology Association Meeting (December 10-14, New Orleans) including an oral presentation for BRUKINSA in MZL (MAGNOLIA trial), and a poster with updated results for BRUKINSA in acalabrutinib-intolerant patients with B-cell malignancies.

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, and for tislelizumab in combination with chemotherapy as a 1L treatment in patients with unresectable locally advanced, recurrent or metastatic ESCC;
- Continue interaction with NMPA for sBLA for tislelizumab as a treatment for 1L hepatocellular carcinoma;
- Continue to support review by regulatory authorities of BeiGene's applications for tislelizumab including: Australia's TGA review and New Zealand's Medsafe review of BLA for tislelizumab in 1L/2L NSCLC and 2L ESCC, and South Korea's MFDS review of BLA for tislelizumab in 2L ESCC;
- In collaboration with Novartis, continue to support review of marketing applications including:
 - Ongoing FDA review of the BLA submission in 2L ESCC including facilitating scheduling the required inspections as soon as possible;
 - EMA review of marketing authorization applications for tislelizumab in 1L/2L NSCLC and 2L ESCC;
 - UK MHRA review of tislelizumab for treatment of 1L/2L NSCLC and 2L ESCC in Great Britain via Reliance route;
 - Swiss Medic review of marketing authorization applications for tislelizumab in 2L ESCC; and
- Support U.S. FDA regulatory submission by Novartis in 2023 for 1L gastric cancer, 1L unresectable ESCC, and 1L HCC.

BGB-11417 (BCL-2)

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

Collaboration Programs

- In collaboration with Zymeworks, announce topline results for a Phase 2b clinical trial of zanidatamab in advanced or metastatic HER2-amplified biliary tract cancers (NCT04466891) 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	
	September 30, 2022	December 31, 2021 ¹
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	\$ 5,072,510	\$ 6,624,849
Accounts receivable, net	189,170	483,113
Inventories	290,911	242,626
Property and equipment, net	681,914	587,605
Total assets	6,726,013	8,535,525
Liabilities and equity:		
Accounts payable	252,071	262,400
Accrued expenses and other payables	410,255	558,055
Deferred revenue	294,883	407,703
R&D cost share liability	319,973	390,362
Debt	649,333	629,678
Total liabilities	2,070,842	2,402,962
Total equity	\$ 4,655,171	\$ 6,132,563

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

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2022	2021¹	2022¹	2021¹
	(Unaudited)		(Unaudited)	
Revenue:				
Product revenue, net	\$ 349,506	\$ 192,461	\$ 915,590	\$ 437,202
Collaboration revenue	38,122	13,979	120,236	525,102
Total revenues	<u>387,628</u>	<u>206,440</u>	<u>1,035,826</u>	<u>962,304</u>
Expenses:				
Cost of sales - products	76,543	47,413	212,953	116,361
Research and development	426,363	351,937	1,194,485	1,028,754
Selling, general and administrative	322,892	269,227	948,868	683,622
Amortization of intangible assets	187	188	563	563
Total expenses	<u>825,985</u>	<u>668,765</u>	<u>2,356,869</u>	<u>1,829,300</u>
Loss from operations	(438,357)	(462,325)	(1,321,043)	(866,996)
Interest income (expense), net	12,759	(2,230)	34,261	(11,275)
Other (loss) income, net	(125,640)	31,477	(243,290)	26,487
Loss before income taxes	<u>(551,238)</u>	<u>(433,078)</u>	<u>(1,530,072)</u>	<u>(851,784)</u>
Income tax expense	6,318	5,036	28,408	15,354
Net loss	<u>(557,556)</u>	<u>(438,114)</u>	<u>(1,558,480)</u>	<u>(867,138)</u>
Net loss per share attributable to BeiGene, Ltd.:				
Basic and diluted	<u>\$ (0.41)</u>	<u>\$ (0.36)</u>	<u>\$ (1.16)</u>	<u>\$ (0.72)</u>
Weighted-average shares outstanding:				
Basic and diluted	<u>1,345,303,747</u>	<u>1,205,971,284</u>	<u>1,337,976,853</u>	<u>1,196,391,201</u>
Net loss per ADS attributable to BeiGene, Ltd.:				
Basic and diluted	<u>\$ (5.39)</u>	<u>\$ (4.72)</u>	<u>\$ (15.14)</u>	<u>\$ (9.42)</u>
Weighted-average ADSs outstanding:				
Basic and diluted	<u>103,484,904</u>	<u>92,767,022</u>	<u>102,921,296</u>	<u>92,030,092</u>

¹ We revised certain prior period financial statements for an error related to the valuation of net deferred tax assets, the impact of which was immaterial to our previously filed financial statements in the first and second quarters of 2022 and the quarterly and annual periods of fiscal 2021 (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 September 30, 2022 filed with the SEC).

About BeiGene

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

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding clinical data for BeiGene's drug candidates and approvals of its medicines; the conduct of late-stage clinical trials and expected data readouts; additional planned product approvals and launches; the advancement of and anticipated clinical development, regulatory approvals and other milestones and commercialization of BeiGene's medicines and drug candidates; the potential for BRUKINSA to provide clinical benefit to patients with CLL compared with the comparator drug; the success of BeiGene's commercialization efforts and revenue growth; the expected capacities and completion dates for the Company's manufacturing facilities under construction; the impact of the COVID-19 pandemic on the Company's clinical development, regulatory, commercial, manufacturing, and other operations; expectations for BeiGene's strategic alliance with Ontada; 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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