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BeiGene Reports First Quarter 2021 Financial Results

- *Recorded product revenue of $106.1 million for the first quarter, compared to $52.1 million in the prior year period*
- *Included in China's National Reimbursement Drug List (NRDL), effective March 1, 2021, significantly driving increased demand for tislelizumab, BRUKINSA®, and XGEVA®*
- *Closed collaboration and license agreement with Novartis for tislelizumab, with $650 million up-front payment*
- *Received approval for Guangzhou biologics manufacturing facility, expanding commercial supply of tislelizumab in China and strategic capabilities*

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CAMBRIDGE, Mass. & BEIJING--(BUSINESS WIRE)--BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a global biotechnology company focused on developing and commercializing innovative medicines worldwide, today reported recent business highlights, anticipated upcoming milestones, and financial results for the first quarter of 2021.

"We continue to make excellent progress across the board in advancing our key strategic objectives, including enhancing our commercial scale in China, working to broaden access to our medicines around the world through new regulatory filings, advancing our pipeline, including potentially first-in-class compounds and wholly owned combinations, and expanding our capabilities in biologics manufacturing. We are encouraged by the performance of our commercial portfolio since the implementation on March 1 of three innovative oncology products in the National Reimbursement Drug List in China," said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. "In addition, we closed our license and collaboration agreement with Novartis, receiving a $650 million up-front payment, and recently announced positive interim results from our global Phase 3 head-to-head ALPINE trial in chronic lymphocytic leukemia, which we believe further demonstrates the differentiated and potentially best-in-class profile for BRUKINSA. We are confident in our strong position to deliver on our mission of providing high quality medicines to billions of more people around the world who need them."

Recent Business Highlights and Upcoming Milestones

Commercial Operations

- Generated $106.1 million in global product revenue in the three months ended March 31, 2021, representing a 104% increase from $52.1 million in the comparable period of

the prior year. Product sales in the first quarter grew over the prior year as well as sequentially compared to the prior quarter due to continued progress in our product launches, including significantly increased patient demand following the inclusion of tislelizumab, BRUKINSA®, and XGEVA® in the NRDL, effective March 1, 2021, which more than offset the net effect of price reductions as a result of NRDL inclusion;

- First quarter product revenue grew sequentially despite a negative adjustment of $24.2 million as a result of the normal process in China of compensating distributors for products previously sold at the pre-NRDL price during the quarter that remained in the distribution channel, due to the first inclusion of tislelizumab, BRUKINSA, and XGEVA in the NRDL. The majority of the compensation related to tislelizumab;
- Inclusion in the NRDL led to significant increases in the number of formal hospital listings for tislelizumab, BRUKINSA, and XGEVA to approximately 4x, 8x, and 6x their respective levels prior to NRDL inclusion; and
- Sales of BRUKINSA in the United States continued steady growth despite the continued impact from COVID-19, including the vaccine rollout, on patient treatment plans.

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 the United States, China, Canada, and other international markets in selected indications and under development for additional approvals globally.*

- Announced positive results from a planned interim analysis of the ongoing Phase 3 ALPINE trial (NCT03734016) comparing BRUKINSA against ibrutinib in adults with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL);
- Received approval and launched BRUKINSA in Canada for the treatment of adult patients with Waldenström's macroglobulinemia (WM), based on the Phase 3 ASPEN trial comparing BRUKINSA and ibrutinib; and
- Continued to advance BRUKINSA in new markets. BRUKINSA is now commercially available in Israel for patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. To-date, more than 30 marketing authorization applications in multiple indications have been submitted outside of the United States and China, covering the European Union (EU) and more than 20 other countries.

Expected Milestones for BRUKINSA

- Announce topline results from the Phase 3 SEQUOIA trial (NCT03336333) comparing BRUKINSA with bendamustine plus rituximab in patients with treatment-naïve CLL/SLL as early as 2021;
- Present interim results from the Phase 3 ALPINE trial (NCT03734016) at a major medical conference in 2021 and announce additional results in 2022;

- Continue to expand BRUKINSA's registration program globally in new geographies and indications, including potential approvals in 2021 for certain patients with MCL in the Middle East, South America, Canada, Australia, and Russia; and with WM in the United States, EU, China, and Australia; and
- Complete enrollment in the pivotal global Phase 2 ROSEWOOD trial (NCT03332017) comparing BRUKINSA and obinutuzumab versus obinutuzumab alone in patients with R/R follicular lymphoma (FL) in 2021.

***Tislelizumab**, a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages; approved in China in selected indications and under development for additional approvals globally.*

- Entered into and closed a collaboration and license agreement with Novartis Pharma AG granting Novartis rights to develop, manufacture and commercialize tislelizumab in North America, Europe, and Japan, and received a $650 million up-front payment;
- Announced the acceptance of a supplemental Biologics License Application (sBLA) by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) for treatment in the second- or third-line setting of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have progressed on prior platinum-based chemotherapy;
- Initiated patient enrollment in the global Phase 2 clinical trial (NCT04716634) of tislelizumab in combination with HUTCHMED (China) Ltd.'s fruquintinib in solid tumors;
- Completed enrollment in the Phase 3 trial (NCT04005716) of tislelizumab with or without platinum chemotherapy plus etoposide in patients with untreated extensive-stage small cell lung cancer; and
- Announced clinical data at the American Association for Cancer Research (AACR) Annual Meeting 2021 from the planned interim analysis of the Phase 3 RATIONALE 303 trial (NCT03358875) of tislelizumab compared to docetaxel as second- or third-line therapy for patients with locally advanced or metastatic NSCLC in an oral presentation.

Expected Milestones for Tislelizumab

- Submit the first biologics license applications (BLA) outside of China in 2021 in collaboration with Novartis;
- Submit sBLAs in China for MSI-H/dMMR solid tumors in the first half of 2021, and for second-line esophageal squamous cell carcinoma (ESCC) in mid-2021;
- Receive approvals in first-line non-squamous NSCLC and second/third-line hepatocellular carcinoma (HCC) in China in 2021;
- Present clinical data at the 2021 ASCO Annual Meeting, including posters on:

  – the RATIONALE 302 trial (NCT03430843) of tislelizumab versus chemotherapy as a second-line treatment for advanced unresectable ESCC; and

– the Phase 2 clinical trial (NCT03736889) of tislelizumab as monotherapy in patients with previously treated, locally advanced unresectable or MSI-high/MRD solid tumors;

- Announce topline results of the Phase 3 trial (NCT03924986) of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment in patients with nasopharyngeal cancer (NPC) in 2021; and
- Complete enrollment in the Phase 3 trial (NCT03957590) of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized ESCC in 2021.

***Pamiparib**, an investigational selective small molecule inhibitor of PARP1 and PARP2*

Expected Milestones for Pamiparib

- Receive approval in China for the treatment of patients with germline *BRCA* mutation-associated advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy, in the first half of 2021;
- Announce topline results from the Phase 3 trial (NCT03519230) of pamiparib as a maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer (OC) in 2021 or the first half of 2022; and
- Present clinical data at the 2021 ASCO Annual Meeting, including posters on:

– the Phase 2 trial (NCT03575065) in China of pamiparib in patients with locally advanced or metastatic HER2-negative breast cancer with germline *BRCA* mutation; and

– the Phase 2 clinical trial (NCT03427814) of pamiparib versus placebo as maintenance therapy in patients with inoperable locally advanced or metastatic gastric cancer that responded to platinum-based first-line chemotherapy.

***Ociperlimab (BGB-A1217)**, an investigational TIGIT monoclonal antibody with competent Fc function*

- Initiated patient enrollment in the following trials:

– the Phase 2 AdvanTIG-202 trial (NCT04693234) of ociperlimab in combination with tislelizumab in patients with previously treated recurrent or metastatic cervical cancer; and

– the Phase 2 AdvanTIG-203 trial (NCT04732494) of ociperlimab in combination with tislelizumab versus tislelizumab in combination with placebo for the second-line treatment of patients with unresectable, locally advanced, recurrent or metastatic ESCC whose tumors have high PD-L1 expression.

Expected Milestones for Ociperlimab

- Present clinical data at the 2021 ASCO Annual Meeting on the Phase 1 dose-escalation study (NCT04047862) of ociperlimab in combination with tislelizumab in patients with advanced solid tumors;
- Initiate patient enrollment in the global Phase 3 AdvanTIG-302 trial (NCT04746924) of ociperlimab in combination with tislelizumab for the first-line treatment of patients with locally advanced, unresectable, or metastatic NSCLC whose tumors have high PD-L1

expression and do not harbor EGFR-sensitizing mutations or ALK translocations, in the first half of 2021; and

- Initiate patient enrollment in the global Phase 3 AdvanTIG-301 trial (NCT04866017) of ociperlimab in combination with tislelizumab and concurrent chemoradiotherapy, in patients with previously untreated, locally advanced unresectable NSCLC in 2021.

Early-Stage Programs

- Announced that the first patient was dosed in a Phase 1 clinical trial (NCT04649385) of BGB-15025, an investigational hematopoietic progenitor kinase 1 (HPK1) inhibitor that is designed to be a potent and highly selective small molecule oral inhibitor of HPK1 and is among the first HPK1 inhibitors to enter the clinic, representing a novel immuno-oncology approach; and
- Continued to advance our early-stage clinical pipeline of internally-developed product candidates, including BGB-11417 (BCL-2 inhibitor in Phase 1 development for cancer), BGB-A445 (non-ligand competing OX40 monoclonal antibody in Phase 1 development in combination with tislelizumab for solid tumors), and BGB-10188 (PI3Kδ inhibitor in Phase 1 development in combination with BRUKINSA or tislelizumab for cancer).

Expected Milestones for Early-Stage Programs

- Initiate a Phase 1 trial (NCT04771130) for BGB-11417, BeiGene's investigational BCL-2 inhibitor, in acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) in 2021. BGB-11417 has been designed to be a potent and selective small molecule Bcl-2 inhibitor; and
- Initiate the Phase 2 portion of the Phase 1/2 trial (NCT03744468) of BGB-A425 in the first half of 2021.

Collaboration with Amgen

- Received acceptance of a sBLA and priority review in China of BLINCYTO® (blinatumomab) for the treatment of children with relapsed or refractory B-cell precursor acute lymphoblastic leukemia.

Other Collaboration Programs

Sitravatinib, an investigational tyrosine kinase inhibitor of receptor tyrosine kinases (RTKs), including TAM family receptors (TYRO3, Axl, MER), split family receptors (VEGFR2, KIT) and RET, licensed from Mirati Therapeutics Inc. (Mirati), in Asia (excluding Japan), Australia, and New Zealand.

- Announced clinical data at AACR on the combination of tislelizumab with sitravatinib, being jointly developed with Mirati, in two oral presentations from two cohorts of a Phase 1b trial (NCT03666143), in patients with unresectable or metastatic melanoma who were

refractory or resistant to PD-1/L1 inhibitors, and in patients with advanced platinum-resistant ovarian cancer (PROC); and

- Completed enrollment in the Phase 1/2 trial (NCT03941873) of sitravatinib as monotherapy and in combination with tislelizumab in patients with locally advanced or metastatic hepatocellular carcinoma (HCC) or gastric/gastroesophageal junction cancer (GC/GEJC).

Expected Milestones for Sitravatinib

- Initiate a Phase 3 trial of sitravatinib in combination with tislelizumab in squamous and non-squamous NSCLC in 2021.

Manufacturing Operations

- Announced approval from the NMPA to begin manufacturing commercial supply of tislelizumab at our state-of-the-art biologics facility in Guangzhou, China. At over one million square feet (100,000 square meters) and 8,000 liters of biologics capacity approved for commercial supply, this wholly owned facility has begun production and distribution of commercial supply of tislelizumab for the China market. An additional phase of construction currently in progress to bring total capacity to 64,000 liters is expected to be completed by the end of 2022.

COVID-19 Impact and Response

- The Company expects that the worldwide health crisis of COVID-19 will continue to have a negative impact on its operations, including commercial sales, regulatory interactions, inspections, filings, and clinical trial recruitment, participation, and data read outs. There remains uncertainty regarding the future impact of the pandemic globally. The Company is striving to minimize delays and disruptions, and continues to execute on its commercial, regulatory and clinical development goals globally.

Corporate Developments

- Announced that Julia Wang has been appointed Chief Financial Officer, effective June 30, 2021. Ms. Wang will succeed Howard Liang, Ph.D., who previously announced his intention to retire from BeiGene and who will stay on through June 30 to ensure an orderly transition; and
- Continued to work on our filing for a proposed public offering and listing of the Company's ordinary shares on the Science and Technology Innovation Board (STAR Market) of the Shanghai Stock Exchange, which is expected to be completed in 2021, subject to market conditions, shareholder approval, and regulatory approvals.

First Quarter 2021 Financial Results

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were $4.8 billion as of March 31, 2021, compared to $4.7 billion as of December 31, 2020, representing an increase of $162.1 million.

- In the three months ended March 31, 2021, cash provided by operating activities was $125.1 million, which included $650.0 million received as an upfront payment from the collaboration agreement with Novartis; capital expenditures were $42.4 million; cash used for upfront license payments was $8.5 million; and cash provided by financing activities was $107.4 million, consisting primarily of bank loans and the exercise of employee share options.

Revenue for the three months ended March 31, 2021 was $605.9 million, compared to $52.1 million in the same period of 2020.

- Product revenues totaled $106.1 million for the three months ended March 31, 2021, compared to $52.1 million in the same period of 2020, and comprised:

  – Sales of tislelizumab in China of $48.9 million, compared to $20.5 million in the prior year period;

  – Sales of BRUKINSA of $22.1 million, compared to $0.7 million in the prior year period;

  – Sales of XGEVA®, the first product transferred to BeiGene from the Amgen collaboration, in China of $14.5 million. BeiGene commenced sales and marketing in China in July 2020;

  – Sales of Bristol Myers Squibb (BMS) in-licensed products in China of $20.3 million, compared to $30.8 million in the same period of the prior year. The reduction in the current year period is due primarily to the lack of product sales of ABRAXANE® following the suspension by the NMPA and voluntary recall by BMS in March 2020; and

- Collaboration revenue for the three months ended March 31, 2021 was $499.8 million, resulting primarily from the partial recognition of the upfront payment of $650.0 million from Novartis. There was no collaboration revenue for the prior year period.

Expenses for the three months ended March 31, 2021 were $535.7 million, compared to $425.8 million in the same period of 2020.

- **Cost of Sales** for the three months ended March 31, 2021 were $32.7 million, compared to $14.1 million in the same period of 2020. Cost of sales increased due to increased product sales of tislelizumab, BRUKINSA and XGEVA, and were partially offset by lower sales of BMS in-licensed products.
- **R&D Expenses** for the three months ended March 31, 2021 were $320.7 million, compared to $304.3 million in the same period of 2020. The increase in R&D expenses was primarily attributable to continued increases in spending on our ongoing and late-stage pivotal clinical trials, the preparation for additional regulatory submissions, and manufacturing costs related to development programs and pre-commercial activities. Upfront fees related to in-process R&D for in-licensed product candidates decreased $34.5 million to $8.5 million for the three months ended March 31, 2021, compared to $43.0 million for the same period of 2020. R&D-related share-based compensation

expense was $21.9 million for the three months ended March 31, 2021, compared to $20.4 million for the same period of 2020.

- **SG&A Expenses** for the three months ended March 31, 2021 were $182.1 million, compared to $107.1 million in the same period of 2020. The increase in SG&A expenses was primarily attributable to increased headcount and increased external expenses related to the growth of our global commercial organization, as we continue to build our worldwide footprint. SG&A-related share-based compensation expense was $23.9 million for the three months ended March 31, 2021, compared to $17.9 million for the same period of 2020.
- **Net Income** for the three months ended March 31, 2021 was $66.5 million, compared to a net loss of $363.7 million in the prior year period. For the three months ended March 31, 2021, basic and diluted earnings per share were $0.06 and $0.05, respectively, and basic and diluted earnings per American Depositary Share (ADS) were $0.73 and $0.69, respectively. For the three months ended March 31, 2020, net loss per share was $0.36 per share, or $4.70 per ADS.

Financial Summary

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

(Amounts in thousands of U.S. Dollars)

	As of	
	March 31, 2021	**December 31, 2020**
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 4,820,878	$ 4,658,730
Accounts receivable, net	84,010	60,403
Working capital	4,028,437	3,885,491
Property and equipment, net	373,949	357,686
Total assets	5,821,004	5,600,757
Liabilities and equity:		
Accounts payable	146,923	231,957
Accrued expenses and other payables	312,134	346,144
Deferred revenue	150,245	—
Debt	598,062	518,652
Total liabilities	1,817,417	1,731,514
Total equity	$ 4,003,587	$ 3,869,243

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,	
	2021	2020
	(Unaudited)	
Revenue:		
Product revenue, net	$ 106,117	$ 52,059
Collaboration revenue	499,755	—
Total revenues	605,872	52,059
Expenses:		
Cost of sales - products	32,685	14,149
Research and development [1]	320,726	304,302
Selling, general and administrative	182,106	107,081
Amortization of intangible assets	188	283
Total expenses	535,705	425,815
Income (loss) from operations	70,167	(373,756)
Interest (expense) income, net	(4,179)	6,690
Other (expense) income, net	(4,123)	3,681
Income (loss) before income taxes	61,865	(363,385)
Income tax (benefit) expense	(4,630)	1,554
Net income (loss)	66,495	(364,939)
Less: Net loss attributable to noncontrolling interest	—	(1,204)
Net income (loss) attributable to BeiGene, Ltd.	$ 66,495	$ (363,735)
Net income (loss) per share attributable to BeiGene, Ltd.:		
Basic	$ 0.06	$ (0.36)
Diluted	$ 0.05	$ (0.36)
Weighted-average shares outstanding:		
Basic	1,188,943,726	1,005,347,581
Diluted	1,257,489,671	1,005,347,581
Net income (loss) per ADS attributable to BeiGene, Ltd.		
Basic	$ 0.73	$ (4.70)
Diluted	$ 0.69	$ (4.70)
Weighted-average ADSs outstanding:		
Basic	91,457,210	77,334,429
Diluted	96,729,975	77,334,429

[1] Research and development expense for the first quarter ended March 31, 2021 and 2020 includes upfront fees related to in-process research and development of in-licensed assets totaling $8.5 million and $43.0 million, respectively.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are committed to expediting the development of our diverse pipeline of novel therapeutics through collaborations or our own internal capabilities, with the aspirational goal of radically improving access to medicines for two billion more people by 2030. BeiGene is a headquarter-less company by design, with a growing global team of approximately 6,000 colleagues across five continents. To learn more about BeiGene, please visit 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 milestones and commercialization of BeiGene's medicines and drug candidates; the success of BeiGene's commercialization efforts and revenue growth; the expected completion date of an additional phase of construction of the Company's biologics facility in Guangzhou, China; the timeline for the Company to complete its proposed public offering and listing on the STAR Market of the Shanghai Stock Exchange, if at all; the impact of the COVID-19 pandemic on the Company's clinical development, regulatory, commercial and other operations; BeiGene's plans and the expected events and milestones under the caption "Recent Business Highlights and Upcoming Milestones"; and BeiGene's plans, commitments, aspirations and goals under the captions "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 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 and other operations, as well as 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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