BeiGene Reports Third Quarter 2021 Financial Results

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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 third quarter and nine months ended September 30, 2021.

“We remain focused on translating science into highly impactful medicines and making these medicines more affordable and accessible to many more people with cancer around the world,” said John V. Oyler, Co-Founder, Chairman and Chief Executive Officer of BeiGene. “In the third quarter we had two new indications approved for BRUKINSA in the United States, and recent BRUKINSA approvals in Australia, Singapore, Brazil, Russia, and Chile as well as a positive CHMP opinion for our first BRUKINSA filing in Europe. Tislelizumab’s BLA for esophageal squamous cell carcinoma (ESCC) has been accepted for review by the FDA, which is the first filing for our internally developed anti-PD-1 medicine outside of China and an important achievement in our collaboration with Novartis. This is one of many global tislelizumab studies that comprise a comprehensive PD-1 program that has enrolled over 5,600 patients in more than 30 countries and regions and includes over 1,700 patients from outside of China. We also continued to expand and strengthen our strategic competitive advantages that we feel are critical to transform the industry and bring innovative and accessible medicines to billions more people around the world. These include research, predominantly CRO-free global clinical development, global commercial infrastructure, and internal manufacturing capabilities.”

Recent Business Highlights and Upcoming Milestones

Commercial Operations

- Product sales increased 111% in the third quarter of 2021 compared to the prior year period, primarily due to increased sales of our internally developed products and in-licensed products from Amgen;
- Global sales of BRUKINSA totaled $65.8 million in the third quarter, representing a 320% increase compared to the prior year period; U.S. sales of BRUKINSA totaled $33.7 million in the third quarter compared to $5.7 million in the comparable prior year period. U.S. sales continued to accelerate in the quarter, driven by continued uptake in mantle cell lymphoma (MCL) and the recent FDA approvals in Waldenström’s macroglobulinemia (WM) and marginal zone lymphoma (MZL). BRUKINSA sales in China totaled $32.1 million in the third quarter, representing growth of 223% compared to the prior year period, driven by a significant increase in all approved indications, including chronic lymphocytic leukemia (CLL);

- Sales of tislelizumab in China totaled $77.0 million in the third quarter, representing a 54% increase compared to the prior year period. In the third quarter, new patient demand from broader reimbursement and further expansion of our salesforce and hospital listings continued to drive increased market penetration and market share for tislelizumab;
- The commercial organization in China continued to demonstrate its ability to bring new products to market, launching the second product from the Amgen collaboration, BLINCYTO® (blinatumomab), which contributed $5.0 million of sales in the third quarter. Two additional new products are expected to be approved or launched by the end of the year; and
- We are preparing for the upcoming National Reimbursement Drug List (NRDL) negotiation in China for our eligible medicines, including tislelizumab in first-line non-squamous non-small cell lung cancer (NSCLC), first-line squamous NSCLC and second- or third-line hepatocellular carcinoma (HCC), BRUKINSA in WM, and pamiparib in germline BRCA (gBRCA) mutation-associated recurrent advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy. The NRDL negotiations are anticipated to be completed in the fourth quarter of 2021.

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 U.S., China, Canada, Australia, and other international markets in selected indications and under development for additional approvals globally.*

- Received FDA approvals in two new indications, including full approval for the treatment of adult patients with WM, and accelerated approval for the treatment of adult patients with relapsed or refractory (R/R) marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen;
- Received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), recommending approval for the treatment of adult patients with WM who have received at least one prior therapy or first-line treatment for patients unsuitable for chemo-immunotherapy;
- Was granted a cohort Temporary Authorization for Use (cATU), an early access program, for patients with WM by the French National Agency for Medicines and Health Products Safety (ANSM);
- Received acceptance of the marketing authorization application (MAA) from Swissmedic and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK for patients with WM;
- Received approval in Australia for the treatment of adult patients with MCL who have received at least one prior therapy and for patients with WM who have received at least one prior therapy or in first line treatment for patients unsuitable for chemo-immunotherapy; and

- Continued to advance BRUKINSA in new markets. BRUKINSA is now approved in Australia, Russia, Singapore, Brazil, Chile, Israel, and UAE for patients with MCL who have received at least one prior therapy. There currently are more than 20 marketing authorization applications in multiple indications under review around the world.

Expected Milestones for BRUKINSA

- Receive EMA approval for treating adult patients with WM who have received at least one prior therapy or first-line treatment for patients unsuitable for chemo-immunotherapy in 2021;
- Report results from the Phase 3 SEQUOIA trial (NCT03336333) comparing BRUKINSA with bendamustine plus rituximab in patients with treatment-naïve CLL or small lymphocytic lymphoma (SLL); and early results from Arm D in patients with del(17p) in combination with venetoclax in two oral presentations at the 63rd American Society of Hematology (ASH) Annual Meeting taking place December 11-14, 2021;
- Continue to discuss Phase 3 clinical trial results in CLL with regulatory agencies in the U.S., Europe, and other countries;
- Report additional results from the Phase 3 ALPINE trial (NCT03734016) in 2022; and
- Continue to expand BRUKINSA's registration program globally in new geographies and indications, including potential additional approvals in 2021 and the first half of 2022 for certain patients with MCL in APAC, the Middle East and South America.

***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.*

- Received acceptance by the FDA of a BLA for tislelizumab in collaboration with Novartis as a treatment for patients with unresectable recurrent locally advanced or metastatic ESCC after prior systemic therapy. The Prescription Drug User Fee Act (PDUFA) target action date is July 12, 2022;
- Received acceptance by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) of a supplemental BLA (sBLA) in combination with chemotherapy as a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer (NPC);
- Received approval from the NMPA in a new indication, for front-line squamous NSCLC with nab-paclitaxel and carboplatin; and
- Reported data at the European Society for Medical Oncology (ESMO) Congress 2021 including:

– RATIONALE 304 (NCT03663205): Tislelizumab plus chemotherapy vs. chemotherapy alone as first-line treatment for non-squamous NSCLC in patients who are smokers vs. non-smokers; and

– RATIONALE 307 (NCT03594747): Tislelizumab plus chemotherapy vs. chemotherapy alone as first-line treatment for advanced squamous NSCLC in patients who were smokers vs. non-smokers.

Expected Milestones for Tislelizumab

Receive approvals in China for the four sBLAs currently under review in first-line NPC, second- or third-line NSCLC, second-line ESCC, and second- or third-line MSI-High solid tumors in 2022.

***Pamiparib**, a selective small molecule inhibitor of PARP1 and PARP2 conditionally approved 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.*

Expected Milestones for Pamiparib

Report topline results from the Phase 3 trial (NCT03519230) of pamiparib as a maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer, in 2021 or the first half of 2022.

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

Initiated patient enrollment in the Phase 2 AdvanTIG-206 trial (NCT04948697) of ociperlimab in combination with tislelizumab plus Bio-Thera's POBEVCY® (BAT1706), a *biosimilar* to bevacizumab (Avastin®), as first-line treatment in patients with advanced HCC.

Expected Milestones for ociperlimab

Initiate patient enrollment in the global Phase 2 AdvanTIG-205 trial (NCT05014815) in frontline stage IV NSCLC, in 2021.

***BGB-11417,** an investigational BCL-2 inhibitor*

Initiated patient enrollment in a Phase 1 trial (NCT04973605) in patients with multiple myeloma with t (11;14) translocation, in 2021.

Expected Milestones for BGB-11417

Begin patient enrollment in pivotal trials, in 2022.

Early-Stage Programs

- 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 or in combination with tislelizumab in solid tumors), 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);

- BGB-16673 (an investigational Chimeric Degradation Activating Compound, or CDAC, targeting BTK) received investigational new drug (IND) clearance and permission to proceed from the FDA. Patient dosing in the first Phase 1 trial (NCT05006716) in patients with B-cell malignancies is expected to begin in 2021; and
- BGB-A425 (an investigational TIM3 monoclonal antibody) study advanced to the Phase 2 portion of the Phase 1/2 trial (NCT03744468) in combination with tislelizumab.

Collaboration with Amgen

Secured approval by the Hainan BoAo government for early access to LUMAKRAS® (sotorasib, a KRAS G12C inhibitor) in designated hospitals in the province.

Other Collaboration Programs

- Announced that the NMPA granted QARZIBA® (dinutuximab beta) conditional approval for the treatment of high-risk neuroblastoma in patients aged 12 months and above who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with a history of R/R neuroblastoma with or without residual disease. QARZIBA is a targeted immunotherapy licensed by EUSA Pharma to BeiGene in mainland China;
- Received notification by BMS-Celgene of its intent to terminate a license and supply agreement with respect to ABRAXANE® (nanoparticle albumin-bound paclitaxel) in China. BeiGene contests this action, as it believes that the reasons provided by BMS-Celgene are not valid bases for terminating the agreement with respect to ABRAXANE. Arbitration proceedings are ongoing between the parties regarding BMS-Celgene's failure to ensure the continuity and adequacy of its supply of ABRAXANE under the agreement in accordance with Good Manufacturing Practices (GMP); and
- Received results from the Phase 2 trial (NCT04551898) evaluating investigational SARS-CoV-2 neutralizing antibody BGB-DXP593 in patients with mild to moderate COVID-19, licensed from Singlomics outside of China. The trial did not meet the primary efficacy endpoint of viral load change in nasopharyngeal swabs at Day 8. The license rights of the two Singlomics candidates (DXP593 and DXP604) outside of the U.S. and the development rights of the candidates in the U.S. have been returned to Singlomics under a reversion agreement signed by the parties, with BeiGene retaining U.S. commercial rights.

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.

Reported data at the European Society for Medical Oncology (ESMO) Congress 2021:

− Sitravatinib + tislelizumab in patients with anti-PD-(L)1 refractory/resistant metastatic NSCLC (NCT03666143); and

− Sitravatinib + tislelizumab in patients with metastatic NSCLC (NCT03666143).

Zanidatamab, (ZW25) an investigational bispecific HER2 antibody targeting HER2 in late-stage clinical development with Zymeworks, Inc.

Expected Milestones for Zanidatamab

Initiate a Phase 3 clinical trial in first-line HER2+ gastric cancer, in 2021.

Manufacturing Operations

- Continued efforts to secure geographically diverse manufacturing and supply chain redundancy with the previously announced plans to build a new commercial-stage manufacturing and clinical R&D campus at Princeton West Innovation Park in Hopewell, New Jersey. The acquisition of the property is expected to close in 2021;
- Continued construction on the new small molecule manufacturing campus in Suzhou, China. Phase 1 of construction will bring over 50,000 square meters and 600M solid preparation capacity and is expected to be completed in 2023. Once completed, the total production capacity is expected to increase BeiGene's small molecule manufacturing capability in China by up to six times the current capacity; and
- Two additional 2,000L bioreactors at Boehringer Ingelheim’s facility are available to support commercial production of tislelizumab’s expanding indications in China. This is in addition to BeiGene’s 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 expected to bring total capacity to 64,000 liters, and 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, manufacturing, and clinical development goals globally.

Corporate Developments

- Listing of the Company’s ordinary shares on the Science and Technology Innovation Board (STAR Market) of the Shanghai Stock Exchange is expected to be completed in 2021, subject to market conditions and additional regulatory approvals; and
- Received inclusion in several FTSE Russell indices, including: the FTSE Global Equity Index Large Cap; the FTSE All-World (LM); the FTSE All-Cap (LMS); and the FTSE Total-Cap (LMSμ). In addition, BeiGene was included in the FTSE Developed ESG Low Carbon Select Index, and the FTSE Asia ex Japan ESG Low Carbon Select Index, reflecting the Company’s commitment to sustainability.

Third Quarter 2021 Financial Results

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were $3.9 billion as of September 30, 2021, compared to $4.4 billion as of June 30, 2021, and $4.7 billion as of December 31, 2020.

In the three months ended September 30, 2021, cash used in operating activities was $495.7 million, primarily due to our net loss of $413.9 million and a $89.4 million increase in our net operating assets and liabilities, offset by non-cash charges of $7.5 million; capital expenditures were $67.0 million; and cash provided by financing activities was $109.2 million, consisting primarily of $50 million in proceeds from the sale of shares to Amgen, as well as the exercise of employee share options.

Revenue for the three months ended September 30, 2021 was $206.4 million, compared to $91.1 million in the same period of 2020.

Product revenue totaled $192.5 million for the three months ended September 30, 2021, compared to $91.1 million in the same period of 2020, including:

– Sales of tislelizumab in China of $77.0 million, compared to $49.9 million in the prior year period;

– Sales of BRUKINSA of $65.8 million, compared to $15.7 million in the prior year period;

– Sales of XGEVA® (denosumab), the first product transferred to BeiGene from the Amgen collaboration, in China of $15.7 million, compared to $3.1 million in the prior year period. BeiGene commenced sales and marketing in China in July 2020;

Collaboration revenue for the three months ended September 30, 2021 was $14.0 million, resulting from the partial recognition of previously deferred revenue associated with the upfront payment received from Novartis in the first quarter of 2021. There was no collaboration revenue in the prior year period.

Expenses for the three months ended September 30, 2021 were $668.8 million, compared to $531.2 million in the same period of 2020.

- **Cost of Sales** for the three months ended September 30, 2021 were $47.4 million, compared to $21.1 million in the same period of 2020. Cost of sales increased primarily due to increased product sales of tislelizumab, BRUKINSA, and XGEVA.
- **R&D Expenses** for the three months ended September 30, 2021 were $351.9 million, compared to $349.1 million in the same period of 2020. The increase in R&D expenses was primarily attributable to increases in headcount and external costs related to our investment in discovery and development activities, including our continued efforts to internalize research and clinical trial activities, partially offset by decreased spending on clinical trials related to BRUKINSA, as well as decreased expense related to upfront fees related to in-process R&D. Additionally, R&D-related share-based compensation expense was $31.7 million for the three months ended September 30, 2021, compared to $25.4 million for the same period of 2020.

- **SG&A Expenses** for the three months ended September 30, 2021 were $269.2 million, compared to $160.8 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 continued to build our worldwide footprint. SG&A-related share-based compensation expense was $35.4 million for the three months ended September 30, 2021, compared to $24.9 million for the same period of 2020.
- **Net Loss** for the three months ended September 30, 2021 was $413.9 million, or $0.34 per share, and $4.46 per American Depositary Share (ADS), compared to $425.2 million, or $0.37 per share, and $4.81 per ADS in the same period of 2020.

Financial Summary

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

(Amounts in thousands of U.S. Dollars)

	As of	
	September 30, 2021	**December 31, 2020**
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 3,923,313	$ 4,658,730
Accounts receivable, net	129,584	60,403
Working capital	3,128,400	3,885,491
Property and equipment, net	450,788	357,686
Total assets	5,286,334	5,600,757
Liabilities and equity:		

Accounts payable	206,203	231,957
Accrued expenses and other payables	389,874	346,144
Deferred revenue	124,898	—
R&D cost share liability	420,001	502,848
Debt	643,278	518,652
Total liabilities	1,929,261	1,731,514
Total equity	$ 3,357,073	$ 3,869,243

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

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2021	**2020**	**2021**	**2020**
	(Unaudited)		**(Unaudited)**	
Revenue:				
Product revenue, net	$ 192,461	$ 91,080	$ 437,202	$ 208,774
Collaboration revenue	13,979	—	525,102	—
Total revenues	206,440	91,080	962,304	208,774

Expenses:				
Cost of sales - products	47,413	21,123	116,361	49,579
Research and development [1]	351,937	349,070	1,028,754	939,340
Selling, general and administrative	269,227	160,837	683,622	391,967
Amortization of intangible assets	188	187	563	658
Total expenses	668,765	531,217	1,829,300	1,381,544
Loss from operations	(462,325)	(440,137)	(866,996)	(1,172,770)
Interest (expense) income, net	(2,230)	(614)	(11,275)	7,184
Other income, net	31,477	5,711	26,487	29,368
Loss before income taxes	(433,078)	(435,040)	(851,784)	(1,136,218)
Income tax benefit	(19,223)	(8,423)	(24,083)	(8,344)
Net loss	(413,855)	(426,617)	(827,701)	(1,127,874)

Less: Net loss attributable to noncontrolling interest	—	(1,393)	—	(3,713)
Net loss attributable to BeiGene, Ltd.	$ (413,855)	$ (425,224)	$ (827,701)	$ (1,124,161)
Net loss per share attributable to BeiGene, Ltd.:				
Basic and diluted	$ (0.34)	$ (0.37)	$ (0.69)	$ (1.07)
Weighted-average shares outstanding:				
Basic and diluted	1,205,971,284	1,148,973,077	1,196,391,201	1,052,940,583
Net loss per ADS attributable to BeiGene, Ltd.				
Basic and diluted	$ (4.46)	$ (4.81)	$ (8.99)	$ (13.88)
Weighted-average ADSs outstanding:				
Basic and diluted	92,767,022	88,382,544	92,030,092	80,995,429

[1] Research and development expense for the three and nine months ended September 30, 2021 includes upfront fees related to in-process research and development of in-licensed assets totaling nil and $53.5 million, respectively, compared to $66.5 million and $109.5 million in the comparable prior year periods.

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 expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 7,700 colleagues across five continents. 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 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 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 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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