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BeiGene Reports Second Quarter 2020 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, Aug. 06, 2020 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today reported recent business highlights, anticipated upcoming milestones, and financial results for the second quarter and first half of 2020.

“We have made tremendous progress since the start of the second quarter, with approvals for tislelizumab and BRUKINSA for three indications in China and eight accepted new drug applications for tislelizumab, BRUKINSA, and pamiparib in China, the European Union, Australia, and Israel. Our commercial teams grew product sales to a new quarterly high of approximately $66 million, driven by our recently launched internally developed products,” said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. “We recently completed a very successful registered direct offering in which we raised net proceeds of approximately $2.07 billion and believe that we are well-positioned to accelerate the development of our deep pipeline, further expand our portfolio in oncology and into other therapeutic areas, and continue to build our capabilities and operations for our products to serve more patients worldwide. In the remainder of 2020 and 2021, we look forward to key clinical readouts, as well as expanded commercial opportunities for our products through approvals in additional indications and geographic markets and by growing our commercial-stage portfolio to up to 11 products.”

Recent Business Highlights and Upcoming Milestones

Commercial Operations

- Received approval from the National Medical Products Administration (NMPA) for BRUKINSA® (zanubrutinib) in China in June for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least one prior therapy, and for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. Subsequently launched BRUKINSA in these indications in China within 12 days of approval;

- Received approval from the NMPA and launched tislelizumab in China in April for the treatment of patients with previously treated locally advanced or metastatic urothelial carcinoma (bladder cancer);

- Began commercializing XGEVA® (denosumab) in China on July 1 for the treatment of giant cell tumor of bone (GCTB), following its earlier approval by the NMPA in May 2019 and subsequent launch by Amgen. This marks the first Amgen product that has been transitioned to BeiGene for commercialization in China since the commencement of our global strategic oncology collaboration in January 2020;

- Generated $65.64 million in product revenue in the three months ended June 30, 2020, representing a 13% increase compared to the comparable period of the prior year, despite the suspension and recall of ABRAXANE® in China in March 2020. Product revenue was driven by sales of our newly launched internally developed products tislelizumab and BRUKINSA; and

- Received supplemental medical insurance coverage in Hainan province, China for tislelizumab for patients with classical Hodgkin’s lymphoma (cHL), BRUKINSA for patients with CLL/SLL, and XGEVA for patients with GCTB.

Development Programs

BRUKINSA® (zanubrutinib), *a small molecule inhibitor of Bruton’s tyrosine kinase (BTK) designed to maximize BTK occupancy and minimize off-target effects. BRUKINSA has received accelerated approval in the United States for the treatment of adult patients with MCL who have received at least one prior therapy; and in China in two*

indications – the treatment of adult patients with CLL /SLL who have received at least one prior therapy, and the treatment of adult patients with MCL who have received at least one prior therapy. BRUKINSA is under development globally for additional approvals.

- Announced the acceptance of a marketing authorization application (MAA) by the European Medicines Agency (EMA) for BRUKINSA for the treatment of patients with Waldenström's Macroglobulinemia (WM) who have received at least one prior therapy or as first-line treatment for patients unsuitable for chemo-immunotherapy;

- Presented clinical data from the Phase 3 ASPEN trial comparing BRUKINSA to ibrutinib for the treatment of patients with WM at the 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program;

- Announced an exclusive distribution agreement with Medison Pharma Ltd. in Israel and the acceptance of a new drug application (NDA) in Israel for BRUKINSA for the treatment of patients with MCL who have received at least one prior therapy; and

- Filed and received acceptance of two NDAs by the Australia Therapeutic Goods Administration (TGA) for BRUKINSA in relapsed/refractory (R/R) MCL and WM.

Expected Milestones for BRUKINSA

- File a supplemental new drug application (sNDA) in China for WM in 2020;

- Announce top-line results from the SEQUOIA trial (NCT03336333) comparing BRUKINSA with bendamustine plus rituximab in patients with treatment-naïve CLL or SLL as early as the second half of 2020;

- Discuss data from the Phase 3 ASPEN trial (NCT03053440) comparing BRUKINSA to ibrutinib in patients with WM with the U.S. Food and Drug Administration (FDA) in 2020; and

- Complete expanded enrollment in the Phase 3 ALPINE trial (NCT03734016) comparing BRUKINSA with ibrutinib in patients with R/R CLL/SLL in 2020.

***Tislelizumab**, a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages; approved in China in two indications – the treatment for patients with cHL who received at least two prior therapies, and the treatment of patients with locally advanced or metastatic urothelial carcinoma with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Tislelizumab is under development globally for additional approvals.*

- Announced that the NMPA accepted a sNDA for tislelizumab in combination with chemotherapy for first-line treatment of patients with advanced non-squamous non-small cell lung cancer (NSCLC);

- Announced that the NMPA accepted a sNDA for tislelizumab for the treatment of patients with previously treated unresectable hepatocellular carcinoma (HCC), the most common form of liver cancer;

- Presented results from a Phase 3 clinical trial evaluating tislelizumab in combination with standard chemotherapy for the first-line treatment of patients with advanced squamous NSCLC at the 2020 ASCO Virtual Scientific Program. Data from this trial were included in the sNDA currently under review by the NMPA;

- Initiated patient enrollment in a Phase 3 trial (NCT04379635) in China comparing tislelizumab plus chemotherapy to placebo plus chemotherapy in patients with resectable Stage II or IIIA NSCLC;

- Completed enrollment in the pivotal Phase 2 trial (NCT03736889) in China of patients with mismatched repair deficient (dMMR) or microsatellite instability-high (MSI-H) solid tumors; and

- Entered into a clinical collaboration agreement with Hutchison China MediTech Limited (Chi-Med) to evaluate the safety, tolerability and efficacy of combining tislelizumab with two of Chi-Med's drug candidates, Elunate® (fruquintinib) and surufatinib, for the treatment of various solid tumor cancers in the United States, Europe, China, and Australia.

Expected Milestones for Tislelizumab

- Present data from the Phase 3 trial (NCT03663205) of tislelizumab combined with chemotherapy for the first-line treatment of patients with advanced non-squamous NSCLC at the 2020 European Society for

Medical Oncology (ESMO) Virtual Congress. Data from this trial were included in the sNDA currently under review by the NMPA; and

- Announce top-line results from the global Phase 3 trial (NCT03358875) comparing tislelizumab versus docetaxel in second-or third-line patients with NSCLC and the global Phase 3 trial (NCT03430843) comparing tislelizumab versus chemotherapy in second-line patients with advanced esophageal squamous cell carcinoma (ESCC) in 2020 or early 2021.

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

- Announced that the NMPA accepted and subsequently granted priority review of an NDA for pamiparib for the treatment of patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy.

Expected Milestones for Pamiparib

- Present data from the Phase 1/2 trial (NCT03333915) of pamiparib in patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy, at the 2020 ESMO Virtual Congress. Data from this trial were included in the NDA currently under review by the NMPA; and

- Announce top-line results from the Phase 3 trial (NCT03519230) of pamiparib as a maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer (OC) in 2020 or the first half of 2021.

Early-Stage Clinical Development Programs

- Continued to advance our earlier-stage pipeline of internally-developed assets, including BGB-A1217 (monoclonal antibody against TIGIT in Phase 1/2 development for cancer in combination with tislelizumab), BGB-11417 (BCL-2 inhibitor in Phase 1 development for cancer), BGB-A445 (non-ligand competing OX40 monoclonal antibody in Phase 1 development for solid tumors in combination with tislelizumab), BGB-10188 (PI3Kδ inhibitor in Phase 1 development for cancer in combination with BRUKINSA or tislelizumab), and BGB-15025 (HPK1 inhibitor in preclinical development for cancer); and

- Identified a recommended Phase 2 dose in the Phase 1 trial (NCT04047862) of BGB-A1217 (TIGIT monoclonal antibody) in combination with tislelizumab in advanced solid tumors.

Collaboration Programs

***Zanidatamab (ZW25)**, a novel investigational Azymetric™ bispecific antibody against HER2 currently in Phase 2 clinical development with Zymeworks Inc.*

- Began the manufacturing technology transfer to our biologics facility in Guangzhou.

Expected Milestones for Zanidatamab

- Support clinical development and enrollment of the planned registration-enabling trials in refractory HER2-positive biliary tract cancer in 2020 and first-line HER2-positive gastroesophageal adenocarcinomas in late 2020 or early 2021.

***BGB-3245**, an investigational RAF dimer inhibitor with activity against mutant monomeric and dimeric forms of B-RAF in preclinical studies; being developed by MapKure, which is jointly owned by BeiGene and SpringWorks Therapeutics*

- Initiated patient enrollment in the United States and Australia in the Phase 1 clinical trial (NCT04249843) of BGB-3245 in patients with advanced or refractory solid tumors.

Expected Milestones for BGB-3245

- Initial clinical data from the Phase 1 study expected in 2021.

Manufacturing Facilities

- Completed equipment validation and continued manufacturing process validation for the first phase of our biologics manufacturing facility in Guangzhou; and

- Initiated expansion of the second phase of our biologics manufacturing facility in Guangzhou to significantly increase manufacturing capacity and introduce new manufacturing technology platforms, expected to be

completed by the end of 2020.

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 and inspections, and clinical trial recruitment and participation. Although the impact of COVID-19 on operations in China lessened in the second quarter of 2020 compared to the first quarter of 2020, there remains uncertainty regarding the future impact of the pandemic both in China as well as globally. The Company is striving to minimize delays and disruptions, and continues to execute on its commercialization, regulatory and clinical development goals globally.

Other Developments

- Announced the closing of a registered direct offering of 145,838,979 ordinary shares, at a price of $14.2308 per share ($185 per American Depositary Share (ADS)), resulting in gross proceeds of approximately $2.08 billion and net proceeds, after estimated offering expenses, of approximately $2.07 billion.

- Announced a license and collaboration agreement with Assembly Biosciences, Inc. in China for its portfolio of three clinical-stage chronic hepatitis B virus (HBV) core inhibitor candidates ABI-H0731, ABI-H2158, and ABI-H3733, for the treatment of patients with HBV infection; and

- Announced the appointment of Angus Grant, Ph.D. as Chief Business Executive. Dr. Grant will oversee business development and alliance management and help drive external innovation and investment to guide our global growth strategy.

Second Quarter 2020 Financial Results

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were $3.16 billion as of June 30, 2020, compared to $3.38 billion as of March 31, 2020, and $985.50 million as of December 31, 2019. Our cash balance as of June 30, 2020 does not include net proceeds of approximately $2.07 billion received on July 15, 2020 from a registered direct offering of our ordinary shares to certain existing shareholders.

- In the three months ended June 30, 2020, cash used in operating activities totaled $263.00 million and capital expenditures were $32.61 million, compared to $46.10 million and $21.45 million, respectively, in the prior year period.

Revenue for the three months ended June 30, 2020 was $65.64 million, compared to $243.35 million in the same period of 2019. The decrease in total revenue is primarily attributable to the absence of collaboration revenue after the termination of the Celgene collaboration for tislelizumab in June 2019 and decreased product sales of ABRAXANE in China following the suspension by the NMPA and recall in March 2020, partially offset by sales of tislelizumab in China and BRUKINSA in the United States and China.

- Product revenues totaled $65.64 million for the three months ended June 30, 2020, compared to $58.14 million for the same period in 2019, comprised of:

  - $29.42 million from sales of tislelizumab in China, in its first full quarter of sales following its launch in March 2020;

  - $6.97 million from sales of BRUKINSA in China and the United States, including the launch inventory build at distributors following approval in China in June 2020;

  - $29.01 million from sales of REVLIMID® and VIDAZA® in China, compared to $23.41 million in the same period of the prior year; and

  - $0.24 million from ABRAXANE, which was comprised of reversals of rebate accruals subsequent to the suspension of sales and recall of ABRAXANE in March 2020, compared to $34.73 million in the same period of the prior year.

- Collaboration revenue was nil for the three months ended June 30, 2020, compared to $185.20 million for the same period in 2019. Collaboration revenue for the three months ended June 30, 2019 included a termination fee of $150 million from the termination of the Celgene collaboration agreement for tislelizumab, as well as $25.74 million of research and development service revenue and $9.46 million of reimbursed research and development costs under the agreement, both of which were recognized prior to termination of the agreement.

Expenses for the three months ended June 30, 2020 were $424.51 million, compared to $329.18 million in the same period of 2019.

- **Cost of Sales** for the three months ended June 30, 2020 were $14.31 million, compared to $17.84 million in the same period of 2019. Cost of sales primarily included acquisition costs for supply of REVLIMID and VIDAZA that was sold during the period in China, as well as the post-approval costs of tislelizumab and BRUKINSA that was sold during the period.

- **R&D Expenses** for the three months ended June 30, 2020 were $285.97 million, compared to $228.76 million in the same period of 2019. The increase in R&D expenses was primarily attributable to continued increases in spending on our ongoing and newly initiated late-stage pivotal clinical trials, development expenses associated with the Amgen collaboration, the preparation for additional regulatory submissions, and manufacturing costs related to pre-commercial activities and supply. Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the three months ended June 30, 2020 was $55.94 million, of which $28.34 million was recorded as R&D expense. The remaining $27.61 million was recorded as a reduction of the R&D cost share liability. R&D-related share-based compensation expense was $23.71 million for the three months ended June 30, 2020, compared to $18.15 million for the same period of 2019.

- **SG&A Expenses** for the three months ended June 30, 2020 were $124.05 million, compared to $82.25 million in the same period in 2019. The increase in SG&A expenses was primarily attributable to increased headcount, including the expansion of our commercial team to support the distribution of our products in China and the United States, as well as higher professional service fees and costs to support our growing operations. SG&A-related share-based compensation expense was $21.76 million for the three months ended June 30, 2020, compared to $14.45 million for the same period of 2019.

- **Net Loss** for the three months ended June 30, 2020 was $335.20 million, or $0.33 per share, or $4.31 per ADS, compared to $85.57 million, or $0.11 per share, or $1.43 per ADS in the same period in 2019.

Financial Summary

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

(Amounts in thousands of U.S. Dollars)

	As of	
	June 30, 2020	December 31, 2019
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 3,157,643	$ 985,503
Accounts receivable, net	61,663	70,878
Working capital	2,841,209	862,384
Property and equipment, net	258,106	242,402
Total assets	3,903,290	1,612,289
Liabilities and equity:		
Accounts payable	157,173	122,488
Accrued expenses and other payables	207,921	163,556
Bank loans	157,552	83,311
Shareholder loan	160,164	157,384
Research and development cost share liability	561,594	—
Total liabilities	1,356,798	633,934
Noncontrolling interest	10,194	16,150
Total equity	$ 2,546,492	$ 978,355

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(Unaudited)			
Revenue:				
Product revenue, net	$ 65,635	$ 58,142	$ 117,694	$ 115,563
Collaboration revenue	—	185,204	—	205,616
Total revenues	65,635	243,346	117,694	321,179
Expenses:				
Cost of sales	14,307	17,839	28,456	33,100
Research and development	285,968	228,760	590,270	407,111
Selling, general and administrative	124,049	82,248	231,130	139,893
Amortization of intangible assets	188	332	471	663
Total expenses	424,512	329,179	850,327	580,767
Loss from operations	(358,877)	(85,833)	(732,633)	(259,588)
Interest income, net	1,108	2,886	7,798	7,363
Other income (expense), net	19,976	(878)	23,657	850
Loss before income taxes	(337,793)	(83,825)	(701,178)	(251,375)
Income tax (benefit) expense	(1,475)	2,129	79	2,648
Net loss	(336,318)	(85,954)	(701,257)	(254,023)
Less: Net loss attributable to noncontrolling interest	(1,116)	(384)	(2,320)	(813)
Net loss attributable to BeiGene, Ltd.	$ (335,202)	$ (85,570)	$ (698,937)	$ (253,210)
Net loss per share attributable to BeiGene, Ltd., basic and diluted	$ (0.33)	$ (0.11)	$ (0.69)	$ (0.33)
Weighted-average shares outstanding, basic and diluted	1,010,230,470	777,509,102	1,007,967,904	776,137,299
Net loss per ADS attributable to BeiGene, Ltd., basic and diluted	$ (4.31)	$ (1.43)	$ (9.01)	$ (4.24)
Weighted-average ADSs outstanding, basic and diluted	77,710,036	59,808,392	77,535,993	59,702,869

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 4,200+ employees in China, the United States, Australia, Europe, and elsewhere are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

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 product candidates and approvals of its products; 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 drugs and drug candidates; the success

of BeiGene's commercialization efforts and revenue growth; plans to expand the Company's portfolio in oncology and other therapeutic areas and to expand the Company's capabilities and operations for its products to serve more patients worldwide; the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations; and BeiGene's plans and the expected milestones under the caption "Recent Business Highlights and Upcoming Milestones". 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 products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on the Company's clinical development, 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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