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BeiGene Reports Third Quarter 2019 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, Nov. 12, 2019 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today reported recent business highlights, anticipated upcoming milestones, and financial results for the third quarter and first nine months of 2019.

“We recently announced a transformative collaboration with Amgen that we expect to close in early 2020, at which point we’ll begin executing on the commercialization and development plans for Amgen’s three commercial-stage drugs and 20 drug candidates in China. We believe that this collaboration fortifies our position as the commercialization and development partner of choice in China because of our people, our global reach, and our relentless commitment to patients, to compliance and to quality,” said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. “During this past quarter we continued momentum for our planned upcoming product launches in the U.S. and China. As we look ahead to key catalysts over the rest of the year and into 2020, we’re on track for readouts from up to 10 ongoing Phase 3 or potentially registration-enabling studies in addition to the planned commercial launches.”

Recent Business Highlights and Upcoming Milestones

Clinical Programs

Zanubrutinib, *an investigational small molecule inhibitor of Bruton’s tyrosine kinase (BTK) designed to maximize BTK occupancy and minimize off-target effects*

- Announced U.S. FDA acceptance and priority review of a new drug application (NDA) in patients with relapsed/refractory (R/R) mantle cell lymphoma (MCL) with a Prescription Drug User Fee Act (PDUFA) target action date of February 27, 2020; and

- Initiated the following clinical trials:

  – A global Phase 3 clinical trial (NCT04002297) comparing zanubrutinib plus rituximab to bendamustine plus rituximab in patients with previously untreated MCL who are ineligible for stem cell transplant; and

  – A global Phase 2 clinical trial (NCT04116437) in patients with previously treated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) who are intolerant of prior treatment with ibrutinib.

Expected Milestones for Zanubrutinib

- Present initial results from the 17p deletion arm of the Phase 3 SEQUOIA trial of zanubrutinib with bendamustine plus rituximab in previously untreated patients with CLL/SLL; updated results from a Phase 1/2 trial in R/R CLL/SLL; and updated results from the combination trial of zanubrutinib and tislelizumab in B-cell lymphoid malignancies at the 61st American Society of Hematology meeting (December 7-10, 2019, Orlando, FL);

- Announce top-line results from the Phase 3 ASPEN trial comparing zanubrutinib to ibrutinib in patients with Waldenström’s Macroglobulinemia (WM) in 2019;

- Receive U.S. FDA approval on the New Drug Application (NDA) in patients with R/R MCL, which has a PDUFA date of February 27, 2020;

- Receive approvals in China for the treatment of patients with R/R MCL and R/R CLL/SLL in the first half of 2020;

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

- Announce top-line data from the SEQUOIA trial as early as 2020; and

- Complete enrollment in the Phase 3 ALPINE trial comparing zanubrutinib with ibrutinib in patients with R/R CLL/SLL and in the Phase 2 MAGNOLIA trial in patients with R/R marginal zone lymphoma (MZL) in 2019 or early 2020.

Tislelizumab*, an investigational humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages*

- Completed enrollment in the global Phase 3 clinical trial (NCT03412773) comparing tislelizumab to sorafenib in first-line patients with unresectable hepatocellular carcinoma (HCC);

- Presented data from the Phase 2 clinical trial (NCT04004221) of tislelizumab in patients in China and South Korea with locally advanced or metastatic urothelial carcinoma (UC) at the European Society for Medical Oncology (ESMO) Congress 2019; and

- Presented clinical data at the 22nd Annual Meeting of the Chinese Society of Clinical Oncology (CSCO), including:

  – Results from a Phase 2 trial (NCT03432598) of tislelizumab plus chemotherapy as first-line treatment for patients with lung cancer in China;

  – Updated results from a Phase 2 trial (NCT03469557) of tislelizumab plus chemotherapy in patients with esophageal squamous cell carcinoma (ESCC) in China; and

  – Results from a Phase 1/2 trial (CTR20160872) of tislelizumab in patients in China with advanced solid tumors.

Expected Milestones for Tislelizumab

- Receive NDA approval in China for the treatment of patients with R/R classical Hodgkin's lymphoma (cHL) in 2019;

- Receive sNDA approval in China for the treatment of patients with locally advanced or metastatic UC in 2020;

- Have regulatory discussions based on preliminary results from the global Phase 2 trial (NCT03419897) of tislelizumab in second- or third-line patients with HCC in 2019 or early 2020;

- Announce top-line results from the Phase 3 trial (NCT03594747) comparing tislelizumab plus chemotherapy to chemotherapy alone in first-line patients with squamous non-small cell lung cancer (NSCLC) in China in 2020;

- Announce top-line results from the Phase 3 trial (NCT03663205) comparing tislelizumab plus chemotherapy to chemotherapy alone in first-line patients with non-squamous NSCLC in China in 2020; and

- Complete enrollment in the global portion of the second-line Phase 3 trial (NCT03358875) comparing tislelizumab with docetaxel in patients with NSCLC in 2019 or early 2020 and in the global Phase 3 trial (NCT03430843) comparing tislelizumab with chemotherapy in second-line patients with advanced ESCC in the first half of 2020.

Pamiparib*, an investigational small molecule PARP inhibitor*

- Announced clinical data at ESMO, including:

  – Updated results from the Phase 1b trial (NCT03150810) of pamiparib in combination with low-dose temozolomide in patients with locally advanced or metastatic solid tumors; and

  – Updated dose-escalation/expansion results from the Phase 1 trial (NCT02361723) of pamiparib in patients with advanced solid tumors.

Expected Milestones for Pamiparib

- Have regulatory discussions based on preliminary results from the pivotal Phase 2 trial (NCT03333915) of pamiparib in Chinese patients with previously treated ovarian cancer (OC) in 2020;
- Announce clinical data from the Phase 3 trial (NCT03519230) of pamiparib as a maintenance treatment in patients with platinum-sensitive recurrent OC in 2020;
- Present data from the global Phase 1 trial (NCT02361723) of pamiparib in patients with OC and updated data from the Phase 1 trial (NCT02660034) of pamiparib in combination with tislelizumab in patients with advanced solid tumors in 2020; and
- Submit NDA in China for OC in 2020.

Lifirafenib (BGB-283), *an investigational RAF dimer inhibitor*

- Initiated a Phase 1b trial (NCT03905148) with SpringWorks Therapeutics of lifirafenib in combination with MEK inhibitor mirdametinib (formerly PD-0325901) in patients with advanced or refractory solid tumors.

BGB-A1217, *an investigational TIGIT monoclonal antibody*

- Initiated patient enrollment in a Phase 1a/1b trial (NCT04047862) in China and Australia investigating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of BGB-A1217 in combination with tislelizumab in patients with advanced solid tumors.

BGB-11417*, an investigational small molecule Bcl-2 inhibitor*

- Completed preclinical and investigational new drug (IND) -enabling studies of BGB-11417, which demonstrated potent activity and high selectivity against the pro-apoptotic protein Bcl-2.

Expected Milestone for BGB-11417

- Initiate Phase 1 studies in Australia and the United States to investigate the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of BGB-11417 in patients with mature B-cell malignancies in the first half of 2020.

Manufacturing Facilities

- Completed the initial phase of construction and facility validation, and officially opened our biologics manufacturing facility in Guangzhou, China.

Commercial Operations

- REVLIMID® received formal inclusion on the national reimbursement drug list (NRDL) in China for R/R multiple myeloma;
- In China, preparations for the planned launch of tislelizumab in patients with R/R cHL are ongoing, with field sales training now complete; and
- In the U.S., the commercial field force has been hired in anticipation of the planned launch of zanubrutinib in patients with R/R MCL.

Corporate Developments

- Announced a global strategic oncology collaboration with Amgen to commercialize XGEVA® (denosumab), KYPROLIS® (carfilzomib), and BLINCYTO® (blinatumomab) in China and jointly develop 20 Amgen oncology pipeline assets. Amgen has agreed to purchase approximately $2.7 billion of BGNE shares. The transaction is expected to close in early 2020, subject to approval by a majority vote of the Company's shareholders pursuant to the listing rules of the Hong Kong Stock Exchange, the expiration or termination of applicable waiting periods under applicable antitrust laws, and satisfaction of other customary closing conditions. Shareholders of the Company holding an aggregate of approximately 40% of the outstanding shares have agreed to vote in favor of the transactions; and
- Announced a global license agreement with Seattle Genetics to in-license an advanced preclinical oncology candidate in Asia (except Japan) and the rest of the world other than the Americas (United States, Canada and Latin American countries) and Europe. The agent is expected to advance into clinical trials in the first half of 2020.

Third Quarter 2019 Financial Results

Cash, Cash Equivalents, Restricted Cash and Short-Term Investments were $1.28 billion as of September 30, 2019, compared to $1.56 billion as of June 30, 2019 and $1.81 billion as of December 31, 2018.

- Cash used by operating activities for the three months ended September 30, 2019 was $265.01 million, compared to $132.19 million for the same period in 2018. The increase in the use of cash was primarily attributable to the continued ramp-up in operating expenses in support of our preparation for commercial launch of our late-stage drug candidates in the U.S. and China, continued development of our internal and in-licensed drug candidates, as well as overall organizational growth.

- Capital expenditures were $30.87 million for the three months ended September 30, 2019, which related primarily to the construction of our Guangzhou biologics facility.

Revenue for the quarter ended September 30, 2019 was $50.14 million, compared to $54.20 million in the same period in 2018. The decrease is primarily attributable to the termination of the Celgene collaboration agreement for tislelizumab in the second quarter of 2019, and as a result, the cessation of any related collaboration revenue.

- Product revenue from sales of ABRAXANE®, REVLIMID and VIDAZA® in China totaled $50.14 million for the quarter ended September 30, 2019, compared to $38.45 million for the quarter ended September 30, 2018. Sales in the third quarter of 2019 were negatively impacted by temporary supply disruptions of ABRAXANE.

- Collaboration revenue was nil for the quarter ended September 30, 2019, compared to $15.76 million for the same period in 2018. The decrease is attributable to the termination of the Celgene collaboration agreement on tislelizumab in the second quarter of 2019.

Expenses for the quarter ended September 30, 2019 were $362.41 million, compared to $205.30 million in the same period in 2018.

- **Cost of sales** for the quarter ended September 30, 2019 were $20.11 million, compared to $8.71 million in the same period in 2018. Cost of sales includes the acquisition costs related to the amount of ABRAXANE, REVLIMID and VIDAZA that was sold during the period in China. Costs to manufacture inventory in preparation for commercial launch, incurred prior to regulatory approval, are charged to research and development expense as incurred.

- **R&D Expenses** for the quarter ended September 30, 2019 were $236.97 million, compared to $147.59 million in the same period in 2018. 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, preparation for regulatory submissions, and manufacturing costs related to pre-commercial activities and supply. Employee share-based compensation expense also contributed to the overall increase in R&D expenses, and was $20.67 million for the quarter ended September 30, 2019, compared to $15.52 million for the same period in 2018, due to increased headcount.

- **SG&A Expenses** for the quarter ended September 30, 2019 were $105.00 million, compared to $48.82 million in the same period in 2018. 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 commercial products in China and the planned launches of our late-stage drug candidates in the U.S. and China, as well as higher professional service fees and costs to support our growing operations. The overall increase in SG&A expenses was also attributable to higher SG&A-related share-based compensation expense, which was $16.14 million for the quarter ended September 30, 2019, compared to $9.61 million for the same period in 2018, due to increased headcount.

- **Net Loss** for the quarter ended September 30, 2019 was $307.36 million, or $0.39 per share, or $5.11 per American Depositary Share (ADS), compared to $144.03 million, or $0.19 per share, or $2.53 per ADS in the same period in 2018.

Financial Summary

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

(Amounts in thousands of U.S. Dollars)

	As of	
	September 30,	December 31,

	2019	2018
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 1,276,591	$ 1,809,222
Accounts receivable	55,912	41,056
Working capital	1,169,816	1,697,390
Property and equipment, net	226,499	157,061
Total assets	1,881,070	2,249,684
Liabilities and equity:		
Accounts payable	112,282	113,283
Accrued expenses and other payables	133,020	100,414
Bank loan [1]	104,933	49,512
Shareholder loan [2]	150,758	148,888
Total liabilities	586,833	496,037
Noncontrolling interest	15,759	14,445
Total equity	$ 1,294,237	$ 1,753,647

[1] The bank loan is attributable to (i) BeiGene Guangzhou Biologics Manufacturing Co., Ltd., which totaled $81.15 million as of September 30, 2019, and (ii) a long-term loan from Industrial Bank Co., Ltd. to BeiGene Shanghai.

[2] The shareholder loan is attributable to a RMB900 million convertible note obtained in 2017 from our joint venture partner for the construction and operation of our manufacturing facilities in Guangzhou.

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(unaudited)			
Revenue:				
Product revenue, net	$ 50,141	$ 38,447	$ 165,704	$ 93,123
Collaboration revenue	—	15,755	205,616	46,427
Total revenues	50,141	54,202	371,320	139,550
Expenses:				
Cost of sales – products	(20,106)	(8,706)	(53,206)	(19,512)
Research and development	(236,968)	(147,590)	(644,079)	(421,541)
Selling, general and administrative	(105,002)	(48,820)	(244,895)	(122,895)
Amortization of intangible assets	(331)	(188)	(994)	(563)
Total expenses	(362,407)	(205,304)	(943,174)	(564,511)
Loss from operations	(312,266)	(151,102)	(571,854)	(424,961)
Interest income, net	2,206	4,553	9,569	7,997
Other (expense) income, net	(1,817)	1,585	(967)	2,389
Loss before income taxes	(311,877)	(144,964)	(563,252)	(414,575)
Income tax (expense) benefit	3,217	472	569	7,252
Net loss	(308,660)	(144,492)	(562,683)	(407,323)
Less: Net loss attributable to noncontrolling interest	(1,303)	(461)	(2,116)	(1,809)
Net loss attributable to BeiGene, Ltd.	$ (307,357)	$ (144,031)	$ (560,567)	$ (405,514)
Net loss per share attributable to BeiGene, Ltd., basic and diluted	$ (0.39)	$ (0.19)	$ (0.72)	$ (0.58)

Weighted-average shares outstanding, basic and diluted	781,482,459	739,789,269	777,938,599	703,482,491
Net loss per ADS attributable to BeiGene, Ltd., basic and diluted	$ (5.11)	$ (2.53)	$ (9.37)	$ (7.49)
Weighted-average ADSs outstanding, basic and diluted	60,114,035	56,906,867	59,841,431	54,114,038

About BeiGene

BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly-targeted and immuno-oncology cancer therapeutics. With a team of over 3,000 employees in the United States, China, Australia, and Europe; BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. BeiGene markets ABRAXANE® (nanoparticle albumin–bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) under a license from Celgene Corporation[i].

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 BeiGene's collaboration with Amgen; the conduct of late-stage clinical trials and expected data readouts; the planned commercial launches of BeiGene's product candidates; the advancement of and anticipated clinical development, regulatory milestones and commercialization of BeiGene's products and drug candidates; 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, 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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