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BeiGene Reports Third Quarter 2018 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, Nov. 07, 2018 (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 and financial results for the third quarter and first nine months of 2018.

“We now have three new drug applications currently under review with the China National Medical Products Administration, for zanubrutinib in patients with relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma, as well as mantle cell lymphoma, and for tislelizumab in patients with relapsed/refractory classical Hodgkin’s lymphoma. Our team has accomplished a great deal advancing these promising oncology treatments towards potential commercial availability in China,” said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene.

“The milestones this quarter pave the way for an exciting upcoming year that could further transform BeiGene,” continued Oyler. “We expect to launch two innovative internally developed products in China, as well as have results from our global head-to-head study comparing zanubrutinib to ibrutinib in 2019.”

Recent Business Highlights and Upcoming Milestones

Clinical Programs

Zanubrutinib (BGB-3111)*, an investigational small molecule inhibitor of Bruton’s tyrosine kinase (BTK)*

- We are engaged in a series of continuing discussions with national regulatory authorities regarding new drug applications (NDAs) for zanubrutinib in Waldenström's macroglobulinemia (WM) and other indications. We had previously announced a plan, based on discussions with the U.S. Food and Drug Administration (FDA), to file for accelerated approval in WM in the first half of 2019. Based on recent discussions with the FDA regarding our filing plans, we are revising guidance around the timing of our first NDA filing for zanubrutinib in the United States. We now expect to submit an initial NDA for zanubrutinib in the United States in 2019 or early 2020;

- Submitted and received acceptance from the China National Medical Products Administration (NMPA) for our NDA for patients with relapsed/refractory (R/R) mantle cell lymphoma (MCL);

- Submitted and received acceptance by the NMPA for our NDA for patients with R/R chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL);

- Initiated a global head-to-head Phase 3 trial versus ibrutinib in R/R CLL or SLL;

- Announced updated results from the Phase 1 clinical trial in patients with WM that were presented at the 10th International Workshop on Waldenström's Macroglobulinemia (IWWM). These data, in 73 evaluable patients with WM, continued to demonstrate that zanubrutinib was associated with high rates of overall (92%), major (82%) and very good partial response (VGPR; 41%) and was generally well-tolerated; and

- Announced preliminary results from the Phase 1 clinical trial in Chinese patients with B-cell lymphomas from an oral presentation at the 21st Annual Meeting of the Chinese Society of Clinical Oncology (CSCO).

Expected Upcoming Milestones in 2018

- Present full results of the pivotal Phase 2 trial in Chinese patients with R/R MCL in an oral presentation at the 60th American Society of Hematology (ASH) Annual Meeting, taking place December 1 to 4, 2018 in San Diego, CA;

- BeiGene will hold an investor webcast from ASH on Monday, December 3, at 8:00 pm PST. A live webcast and replay of the event will be available on BeiGene's investor website, http://ir.beigene.com;

- Present updated safety and activity data from a global Phase 1 study in patients with MCL at ASH; and

- Initiate a global Phase 2 trial in patients with R/R marginal zone lymphoma (MZL).

Tislelizumab (BGB-A317)*, an investigational humanized monoclonal antibody against the immune checkpoint receptor PD-1*

- Submitted and received acceptance from the China NMPA of our first NDA for tislelizumab as a treatment for patients with relapsed/refractory classical Hodgkin's lymphoma (R/R cHL);

- Announced preliminary results from the Phase 2 clinical trial in China of tislelizumab combined with chemotherapy as first-line treatment in patients with advanced lung cancer; and announced preliminary results of tislelizumab from the Phase 1/2 clinical trial in China in patients with non-small cell lung cancer from presentations at CSCO and the International Association for the Study of Lung Cancer (IASLC) 19th World Conference on Lung Cancer (WCLC);

- Announced preliminary results from the Phase 1/2 trial in China in patients with microsatellite instability-high (MSI-H) or mismatch repair-deficient (dMMR) solid tumors at CSCO;

- Completed enrollment in the Phase 2 pivotal trial in China for urothelial bladder cancer; and

- Initiated the following trial:

    ° A Phase 2 trial in Chinese patients with MSI-H or dMMR solid tumors.

Expected Upcoming Milestones in 2018

- Present data from the pivotal Phase 2 trial of tislelizumab in Chinese patients with R/R cHL in an oral presentation at ASH;

- Present updated data from expansion cohorts in the Phase 1 trial at the European Society for Medical Oncology Immuno-Oncology (ESMO IO) congress; and

- Initiate additional global randomized frontline pivotal Phase 3 clinical trials in gastric and esophageal cancers in 2018 or early 2019, as well as additional pivotal trials in China in 2019.

Pamiparib (BGB-290)*, an investigational small molecule PARP inhibitor*

- Announced preliminary clinical data from an ongoing Phase 1 trial of pamiparib in combination with temozolomide in patients with locally advanced or metastatic solid tumors that were presented at the European Society for Medical Oncology (ESMO) 2018 Congress.

Expected Upcoming Milestones in 2018

- Present Phase 1/2 trial data on pamiparib in combination with radiation therapy and/or temozolomide in patients with newly diagnosed or recurrent/refractory glioblastoma in an oral presentation at the 23rd Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology (SNO), being held November 15-18 in New Orleans, LA.

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 in Asia (excluding Japan), Australia, and New Zealand*

- Initiated a Phase 1 trial in China and Australia in combination with tislelizumab in patients with advanced solid tumors.

Commercial Programs in China

- Generated $38.45 million in product revenue from sales in China of ABRAXANE®, REVLIMID® and VIDAZA® in the third quarter of 2018, a 22% increase quarter-over-quarter, and 146% growth compared to the fourth quarter of 2017, the first full quarter following the license of these products from Celgene; and

- Received national reimbursement in China from the State Medical Insurance Administration (SMIA) for VIDAZA® (azacitidine for injection) for the treatment of patients with intermediate-2 / high-risk myelodysplastic syndrome (MDS), acute myeloid leukemia (AML) with 20-30% bone marrow blasts and chronic myelomonocyte leukemia (CMML).

Corporate Developments

- Announced a global clinical collaboration with MEI Pharma, Inc. to evaluate the safety and efficacy of MEI's ME-401, an investigational PI3K delta inhibitor, in combination with zanubrutinib for the treatment of patients with B-cell malignancies;

- Announced a global clinical collaboration with SpringWorks Therapeutics to evaluate the safety, tolerability, and preliminary efficacy of combining lifirafenib and SpringWorks Therapeutics' investigational MEK inhibitor, PD-0325901, in patients with advanced solid tumors; and

- Appointed Dr. Jian (Jonathan) Liu as Senior Vice President of Bio-Manufacturing. Prior to joining BeiGene, Dr. Liu served on the Senior Leadership Team of Johnson & Johnson (J&J) Global Pharmaceutical Development & Manufacturing Sciences (PDMS) and China R&D, respectively, responsible for PDMS business strategy development and regional execution.

Third Quarter 2018 Financial Results

Cash, Cash Equivalents, Restricted Cash and Short-Term Investments were $2.10 billion as of September 30, 2018, compared to $1.40 billion as of June 30, 2018 and $837.52 million at December 31, 2017. The increase from the last quarter was primarily due to the net proceeds of $869.71 million from our global offering and listing on the Hong Kong Stock Exchange. Cash, cash equivalents, restricted cash and short-term investments as of September 30, 2018 include approximately $143.16 million held by our 95%-owned joint venture, BeiGene Biologics, to build a commercial biologics manufacturing facility under construction in Guangzhou, China, which includes restricted cash of $36.26 million related to BeiGene Biologics' secured deposits.

Cash used by operations for the three months ended September 30, 2018 was $132.19 million, compared to cash generated by operations of $6.60 million for the same period in 2017. The increase in the use of cash was primarily attributable to the continued ramp-up in operating expenses in support of our ongoing and newly initiated late-stage pivotal clinical programs, preparation for regulatory filings and commercial launch of our late-stage drug candidates, and organizational growth, offset in part by revenue from product sales in China; in the prior period in 2017, cash generated by operations reflected receipt of the up-front payment from Celgene Corporation in connection with our license agreement for tislelizumab. Capital expenditures for the three months ended September 30, 2018 were $26.72 million, compared to $18.79 million for the same period in 2017. The increase was primarily attributable to the continued buildout of our manufacturing facility in Guangzhou.

Revenue for the three months ended September 30, 2018 was $54.20 million, compared to $220.21 million in the same period in 2017. The decrease is primarily attributable to the upfront payment recognized in the prior year period under our collaboration agreement with Celgene for tislelizumab.

- Product revenue from sales of ABRAXANE®, REVLIMID® and VIDAZA® in China totaled $38.45 million for the third quarter of 2018, compared to $31.43 million for the three months ended June 30, 2018, and $8.82 million for the three months ended September 30, 2017 (which only included one month of product sales following the in-license from Celgene), respectively.

- Collaboration revenue totaled $15.76 million for the third quarter of 2018, compared to $21.38 million for the three months ended June 30, 2018, and $211.39 million for the three months ended September 30, 2017, respectively. The decrease, compared to the second quarter of 2018, is primarily due to lower research and development costs in the period on clinical trials that are being reimbursed by Celgene. The decrease, compared to the third quarter of 2017, is due primarily to the upfront revenue recognized in the third quarter of 2017 from the Celgene collaboration.

Expenses for the three months ended September 30, 2018 were $205.30 million, compared to $105.31 million in the quarter ended September 30, 2017, consisting primarily of the following:

- **Cost of sales** for the three months ended September 30, 2018 were $8.71 million, compared to $1.94 million in the third quarter of 2017 (which only included one month of sales), an increase of 348.97 percent. Cost of sales relates to the cost of acquiring ABRAXANE®, REVLIMID® and VIDAZA® for distribution in China.

- **R&D Expenses** for the three months ended September 30, 2018 were $147.59 million, compared to $87.66 million in the same period in 2017, an increase of 68.4%. The increase in R&D expenses was primarily attributable to increased spending on our ongoing and newly initiated late-stage pivotal clinical trials,

preparation for regulatory filings and commercial launch of our late-stage drug candidates, manufacturing costs related to pre-commercial activities and supply, as well as increases in spending related to our preclinical-stage programs. The overall increase in R&D expenses was also attributable to increased R&D-related employee share-based compensation expense, which was $15.52 million for the three months ended September 30, 2018, compared to $10.38 million for the same period in 2017, due to increased headcount and a higher share price.

- **SG&A Expenses** for the three months ended September 30, 2018 were $48.82 million, compared to $15.64 million in the same period in 2017, an increase of 212.1%. 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 existing commercial products in China and the potential launches of our late-stage drug candidates, higher professional service fees and costs to support our growing operations, and higher SG&A-related share-based compensation expense, which was $9.61 million for the three months ended September 30, 2018, compared to $2.95 million for the same period in 2017, due to increased headcount and a higher share price.

- **Net Loss** for the third quarter of 2018 was $144.03 million, or $2.53 per American Depositary Share (ADS), compared to net income of $117.39 million, or $2.79 per ADS in the same period in 2017. For the third quarter of 2018, net loss per ordinary share was $0.19, compared to net income of $0.21 in the same period in 2017.

Financial Summary

Select Condensed Consolidated Balance Sheet Data (U.S. GAAP)
(Amounts in thousands of U.S. Dollars)

	As of	
	September 30, 2018 (unaudited)	December 31, 2017 (audited)
Cash, cash equivalents, restricted cash and short-term investments	$ 2,101,072	$ 837,516
Accounts receivable	37,372	29,428
Unbilled receivables	4,878	—
Working capital	1,991,771	763,509
Property and equipment, net	111,262	62,568
Total assets	2,408,627	1,046,479
Accounts payable	85,552	69,779
Accrued expenses and other payables	75,882	49,598
Bank loan [1]	49,560	18,444
Shareholder loan	146,409	146,271
Total liabilities	425,196	362,248
Noncontrolling interest	12,985	14,422
Total equity	$ 1,983,431	$ 684,231

[1] The bank loan attributable to BeiGene Biologics, a joint venture that is 95% owned by BeiGene, Ltd, totaled $40.82 million as of September 30, 2018.

Condensed Consolidated Statements of Operations (U.S. GAAP)
(Amounts in thousands of U.S. Dollars, except for number of American Depositary Shares (ADSs) and per ADS data) (unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue				
Product revenue, net	$ 38,447	$ 8,822	$ 93,123	$ 8,822
Collaboration revenue	15,755	211,391	46,427	211,391
Total revenues	54,202	220,213	139,550	220,213
Expenses:				
Cost of sales – products	(8,706)	(1,944)	(19,512)	(1,944)
Research and development	(147,590)	(87,660)	(421,541)	(177,678)
Selling, general and administrative	(48,820)	(15,641)	(122,895)	(35,187)
Amortization of intangible assets	(188)	(63)	(563)	(63)
Total expenses	(205,304)	(105,308)	(564,511)	(214,872)
(Loss) income from operations	(151,102)	114,905	(424,961)	5,341
Interest income (expense), net	4,553	(1,785)	7,997	(3,581)
Other income, net	1,585	1,103	2,389	1,541
(Loss) income before income taxes	(144,964)	114,223	(414,575)	3,301
Income tax benefit	472	3,061	7,252	2,680
Net (loss) income	$ (144,492)	$ 117,284	$ (407,323)	$ 5,981
Less: Net loss attributable to noncontrolling interest	(461)	(102)	(1,809)	(237)
Net (loss) income attributable to BeiGene, Ltd.	$ (144,031)	$ 117,386	$ (405,514)	$ 6,218
Net (loss) income attributable to Beigene, Ltd. per ADS:				
Basic	$ (2.53)	$ 2.79	$ (7.49)	$ 0.15
Diluted	$ (2.53)	$ 2.54	$ (7.49)	$ 0.14
Weighted-average ADSs outstanding:				
Basic	56,906,867	42,118,973	54,114,038	40,563,845
Diluted	56,906,867	46,200,975	54,114,038	43,172,139
Net (loss) income per share attributable to BeiGene, Ltd.				
Basic	$ (0.19)	$ 0.21	$ (0.58)	$ 0.01
Diluted	$ (0.19)	$ 0.20	$ (0.58)	$ 0.01
Weighted-average ordinary shares outstanding:				
Basic	739,789,269	547,546,656	703,482,491	527,329,985
Diluted	739,789,269	600,612,680	703,482,491	561,237,818

Condensed Consolidated Statements of Comprehensive Loss (U.S. GAAP)
(Amounts in thousands of U.S. Dollars) (unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net (loss) income	$ (144,492)	$ 117,284	$ (407,323)	$ 5,981
Other comprehensive loss, net of tax of nil:				
Foreign currency translation adjustments	(4,217)	341	(1,912)	985
Unrealized holding gain, net	354	51	1,402	58

Comprehensive (loss) income	(148,355)	117,676	(407,833)	7,024
Less: Comprehensive loss attributable to noncontrolling interests	(486)	(70)	(1,812)	(178)
Comprehensive (loss) income attributable to BeiGene, Ltd.	$ (147,869)	$ 117,746	$ (406,021)	$ 7,202

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 1,700 employees in China, the United States, Australia and Switzerland, 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) in China 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 the encouraging clinical data for BeiGene's product candidates and product revenue for its products; the advancement of and anticipated clinical development and regulatory milestones for its product candidates; and our 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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