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BeiGene Reports First Quarter 2019 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, May 09, 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 first quarter of 2019.

“We made good progress in each of our business areas, including strong commercial performance in the first quarter of 2019, as we prepare for our planned launches in China and first new drug application in the United States. Our team is continuing to expand across the globe, with new trials, new indications, and importantly, new hope for patients with cancer who may not have had access or options for treating their disease,” said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene.

Recent Business Highlights and Upcoming Milestones

Clinical Programs

***Zanubrutinib (BGB-3111)**, an investigational small molecule inhibitor of Bruton’s tyrosine kinase (BTK) designed to maximize BTK occupancy and minimize off-target effects*

Expected Milestones in 2019

- Receive approvals in China for the treatment of patients with relapsed or refractory (R/R) mantle cell lymphoma (MCL) and R/R chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL);
- Submit an initial New Drug Application (NDA) for zanubrutinib in the U.S. in 2019 or early 2020;
- Announce top-line results from the pivotal Phase 2 trial in Chinese patients with Waldenström macroglobulinemia (WM) and submit an NDA in China for WM;
- Achieve first patient dosing in a Phase 1b trial conducted by MEI Pharma of zanubrutinib in combination with ME-401, an investigational selective oral phosphatidylinositol 3-kinase (PI3K) delta inhibitor;
- Complete enrollment of the Phase 3 trial of zanubrutinib compared to bendamustine plus rituximab in patients with previously untreated CLL or SLL;
- Present data from the non-randomized MYD88WT cohort of the Phase 3 trial in WM;
- Announce top-line results from the randomized cohort of the Phase 3 trial comparing zanubrutinib to ibrutinib in patients with WM; and
- Present updated data from the global Phase 1 trial in WM and MCL; pivotal data from the China Phase 2 trials in R/R MCL and R/R CLL/SLL; data from Phase 1 obinutuzumab combination data in CLL/SLL; updated data from the Phase 1 obinutuzumab combination trial in non-Hodgkin’s lymphoma (NHL); and updated data from the global Phase 1 trial in CLL/SLL.

***Tislelizumab (BGB-A317)**, an investigational humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages*

- Announced Phase 1 long-term exposure data and results from the structural and mechanistic analyses at the American Association for Cancer Research (AACR) Annual Meeting in April 2019; and

- Initiated a Phase 3 front-line trial in China of tislelizumab combined with chemotherapy compared to placebo with chemotherapy in patients with recurrent or metastatic nasopharyngeal cancer.

Expected Milestones in 2019

- Receive NDA approval in China for treatment of patients with R/R classical Hodgkin's lymphoma (cHL);
- Present preliminary results of tislelizumab in Chinese patients with nasopharyngeal cancer at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting, being held in Chicago May 31 - June 4;
- Announce top-line results from the pivotal Phase 2 trial in Asian patients with urothelial carcinoma (UC) and file an NDA for UC in China;
- Announce top-line results from the global Phase 2 trial in second- or third-line patients with hepatocellular carcinoma (HCC) and have regulatory discussions;
- Present updated China pivotal Phase 2 data in R/R cHL; updated Phase 2 chemotherapy combination data; and Phase 1 data from China trials; and
- Complete or nearly complete enrollment in all four ongoing Phase 3 trials in lung and liver cancers.

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

Expected Milestones in 2019

- Announce top-line results from the pivotal Phase 2 trial in Chinese patients with previously treated ovarian cancer in late 2019 or early 2020; and
- Present data from the global Phase 1 trial in patients with ovarian cancer and Phase 1 combination data in patients with solid tumors or glioblastoma multiforme.

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

- In collaboration with SpringWorks Therapeutics, Inc., initiated a Phase 1b combination trial of lifirafenib in combination with PD-0325901, an investigational MEK inhibitor in patients with advanced or refractory solid tumors that harbor RAS mutations, RAF mutations, and other MAPK pathway aberrations.

Manufacturing Facilities

- Substantially completed equipment installation and validation of GE Healthcare's KUBio™ technology-based biologics manufacturing facility in Guangzhou, China.

Commercial Operations

- Generated $57.42 million in product revenue in the three months ended March 31, 2019, from sales in China of ABRAXANE®, REVLIMID® and VIDAZA®, which represents a 147% increase compared to the same period in 2018 and a 52% sequential growth compared to the previous quarter; and
- Received supplementary medical insurance coverage for REVLIMID from Zhuhai, Guangdong province, China.

Corporate Developments

- Announced a global collaboration agreement with BioAtla, LLC, for the development, manufacturing, and commercialization of BioAtla's investigational Conditionally Active Biologic (CAB) CTLA-4 antibody (BA3071). BA3071 is a novel, CTLA-4 inhibitor that is designed to be conditionally activated in the tumor microenvironment in order to reduce systemic toxicity and potentially enable safer combinations with checkpoint inhibitors. Subject to regulatory clearance of the Investigational New Drug (IND) application, a Phase 1/2 multi-center, open-label study designed to evaluate the safety, tolerability, pharmacokinetics, immunogenicity, and antitumor activity of BA3071 alone and in combination with tislelizumab is anticipated to start in the second half of 2019; and
- Announced a global research and development collaboration with Ambrx, Inc. to develop next-generation biologics utilizing Ambrx's proprietary Expanded Genetic Code technology platforms designed to allow the efficient incorporation of non-natural amino acids into proteins in both E. Coli (ReCODE™) and CHO cells (EuCODE™) for precision protein engineering.

First Quarter 2019 Financial Results

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were $1.64 billion as of March 31, 2019, compared to $1.81 billion as of December 31, 2018.

- The decrease of $171.67 million in the first quarter of 2019 was primarily due to $171.98 million of cash used in operating activities, $29.00 million of upfront payments made under collaboration agreements, and $21.83 million for investments in property, plant and equipment primarily attributable to the build-out of the Guangzhou biologic manufacturing facility. The decrease was partially offset by $36.70 million in proceeds from an additional drawdown under our Guangzhou factory loan.

Revenue for the first quarter ended March 31, 2019 was $77.83 million, compared to $32.54 million in the same period in 2018. The increase is attributable to increased product revenue in China and collaboration revenue under our license and collaboration agreements with Celgene.

- Product revenue from sales of ABRAXANE®, REVLIMID® and VIDAZA® in China totaled $57.42 million for the first quarter ended March 31, 2019, compared to $23.25 million for the same period in 2018.

- Collaboration revenue totaled $20.41 million for the first quarter ended March 31, 2019, compared to $9.29 million for the same period in 2018.

Expenses for the first quarter ended March 31, 2019 were $251.59 million, compared to $143.35 million in the same period in 2018.

- **Cost of Sales** for the first quarter ended March 31, 2019 were $15.26 million, compared to $4.55 million in the same period in 2018. Cost of sales related to the cost of acquiring ABRAXANE®, REVLIMID® and VIDAZA® for distribution in China.

- **R&D Expenses** for the first quarter ended March 31, 2019 were $178.35 million, compared to $109.70 million in the same period in 2018. 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 submissions and commercial launch of our late-stage drug candidates, 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 $15.77 million for the first quarter ended March 31, 2019, compared to $12.05 million for the same period in 2018, due to increased headcount.

- **SG&A Expenses** for the first quarter ended March 31, 2019 were $57.65 million, compared to $28.92 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 potential launches of our late-stage drug candidates, 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 $10.62 million for the first quarter ended March 31, 2019, compared to $5.34 million for the same period in 2018, due to increased headcount.

- **Net Loss** for the first quarter ended March 31, 2019 was $167.64 million, or $0.22 per share, or $2.81 per American Depositary Share (ADS), compared to $104.60 million, or $0.16 per share, or $2.03 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	
	March 31, 2019	December 31, 2018
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash, and short-term investments	$ 1,637,550	$ 1,809,222
Accounts receivable	58,976	41,056

Unbilled receivables	6,114	8,612
Working capital	1,557,921	1,697,390
Property and equipment, net	197,806	157,061
Total assets	2,172,232	2,249,684
Liabilities and equity:		
Accounts payable	105,320	113,283
Accrued expenses and other payables	90,737	100,414
Bank loan [1]	86,420	49,512
Shareholder loan [2]	155,174	148,888
Total liabilities	549,553	496,037
Noncontrolling interest	13,910	14,445
Total equity	$ 1,622,679	$ 1,753,647

[1] The bank loan is attributable to BeiGene Biologics, a joint venture that is 95% owned by BeiGene, Ltd., which totaled $77.48 million as of March 31, 2019, and the current portion of long-term debt for a term note secured by our Suzhou manufacturing facility.

[2] The shareholder loan is attributable to a RMB900 million convertible note obtained in 2017 by BeiGene Biologics 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 March 31,	
	2019	2018
	(unaudited)	
Revenue:		
Product revenue, net	$ 57,421	$ 23,250
Collaboration revenue	20,412	9,294
Total revenues	77,833	32,544
Expenses:		
Cost of sales - products	(15,261)	(4,550)
Research and development	(178,351)	(109,700)
Selling, general and administrative	(57,645)	(28,915)
Amortization of intangible assets	(331)	(188)
Total expenses	(251,588)	(143,353)
Loss from operations	(173,755)	(110,809)
Interest income, net	4,477	1,552
Other income, net	1,728	729
Loss before income taxes	(167,550)	(108,528)
Income tax (expense) benefit	(519)	3,412
Net loss	(168,069)	(105,116)
Less: Net loss attributable to noncontrolling interest	(429)	(520)
Net loss attributable to BeiGene, Ltd.	$ (167,640)	$ (104,596)
Net loss per share attributable to BeiGene, Ltd., basic and diluted	$ (0.22)	$ (0.16)
Weighted-average shares outstanding, basic and diluted	774,750,255	670,510,605
Net loss per ADS attributable to BeiGene, Ltd., basic and diluted	$ (2.81)	$ (2.03)
Weighted-average ADSs outstanding, basic and diluted	59,596,173	51,577,739

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 approximately 2,400 employees in China, the United States, 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) 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, regulatory milestones and commercialization of its 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 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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