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BeiGene Reports Second Quarter 2018 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, Aug. 09, 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 second quarter and first half of 2018.

“We continued to make excellent progress with encouraging new clinical data, including initial topline data from pivotal trials for our lead drug candidates, zanubrutinib and tislelizumab,” said John V. Oyler, Founder, Chief Executive Officer and Chairman of BeiGene. “We have also continued to expand our clinical programs and have now enrolled more than 3,000 patients worldwide in over 50 ongoing or planned clinical trials, including 17 pivotal or potentially registration-enabling trials of our drug candidates, with two new Phase 3 trials in China of tislelizumab in first-line non-small cell lung cancer having recently initiated. We are on track to submit new drug applications for zanubrutinib and tislelizumab in China this year and are planning to accelerate the U.S. NDA filing of zanubrutinib by seeking accelerated approval.”

“Our commercial organization in China is expanding its footprint to prepare for potential new product launches, and we have seen good growth of our commercial product revenue in China since the transition of these products to BeiGene since last September,” said Dr. Xiaobin Wu, General Manager of China and President of BeiGene, Ltd.

Recent Business Highlights and Upcoming Milestones

Clinical Programs

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

- Received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of patients with Waldenström macroglobulinemia (WM);
- Announced plans to submit a New Drug Application (NDA) with the FDA in the first half of 2019 to pursue accelerated approval of zanubrutinib for WM based on the results from the ongoing global Phase 1 trial. A final determination to submit the NDA will be made subsequent to the pre-NDA meeting with the FDA after obtaining mature data from the trial this fall;
- Announced preliminary topline data from the independent review of response data from the 86-patient single-arm pivotal Phase 2 trial of zanubrutinib in Chinese patients with relapsed or refractory (R/R) mantle cell lymphoma (MCL). With a median follow-up time of 8.3 months at the data cutoff, the overall response rate was 84 percent, including 59 percent complete response;
- Completed enrollment in the global Phase 3 trial comparing zanubrutinib to ibrutinib in patients with WM; and
- Presented clinical data at the 23rd Congress of the European Hematology Association (EHA), including updated Phase 1 data from patients with WM and pooled safety data from zanubrutinib monotherapy trials.

Expected Upcoming Milestones in 2018

- Submit first NDA in China for MCL later this year;
- Present full results of the pivotal Phase 2 trial in Chinese patients with R/R MCL at an upcoming major medical conference;
- Initiate a global head-to-head Phase 3 trial versus ibrutinib in R/R chronic lymphocytic leukemia; and
- Present updated Phase 1 monotherapy or combination data at medical conferences.

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

- Announced preliminary topline results from the independent review of response data from the pivotal Phase 2 trial of tislelizumab in 70 Chinese patients with R/R classical Hodgkin’s lymphoma (cHL). With a

minimum of 24 weeks of follow-up and a median follow-up time of 7.85 months at the data cutoff, overall response rate was 85.7 percent, including 61.4 percent complete response;
- Completed the dose-escalation phase of the combination trial with zanubrutinib in patients with B-cell malignancies and initiated the dose- expansion phase in 8 patients; and
- Initiated the following trials:
    - Phase 3 trial in China of tislelizumab combined with chemotherapy, as a potential first-line treatment in patients with Stage IIIB or IV non-squamous non-small cell lung cancer (NSCLC); and
    - Phase 3 trial in China of tislelizumab combined with chemotherapy as a potential first-line treatment in patients with Stage IIIB or IV squamous NSCLC.

Expected Upcoming Milestones in 2018

- Submit NDA in China for cHL later this year;
- Complete enrollment in the Phase 2 pivotal trial in China for urothelial carcinoma;
- Present updated Phase 1 data and China pivotal trial data at a medical conference; and
- Initiate additional pivotal trials in 2018 or early 2019.

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

- Initiated the following trials:
    - Global Phase 3 trial as maintenance therapy in patients with inoperable locally advanced or metastatic gastric cancer who responded to platinum-based first-line chemotherapy;
    - Phase 3 trial as maintenance therapy in China in patients with platinum-sensitive recurrent ovarian cancer; and
    - Phase 2 trial in China in patients with metastatic HER2-negative breast cancer with BRCA mutation.

Expected Upcoming Milestones in 2018

- Present updated Phase 1 monotherapy and/or combination data at a medical conference.

***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*

Expected Upcoming Milestones

- Initiate Phase 1 trial in combination with tislelizumab in China in 2018 or early 2019.

***BGB-A425,** an investigational humanized monoclonal antibody against T-cell immunoglobulin and mucin-domain containing-3(TIM-3)*

- Received clearance for an investigational new drug (IND) application in the United States.

Expected Upcoming Milestones in 2018

- Initiate Phase 1/2 trial investigating the safety, tolerability, pharmacokinetics and preliminary antitumor activity in combination with tislelizumab in patients with advanced solid tumors.

Commercial Programs

- Generated 35% increase in quarter-over-quarter revenue from sales in China of ABRAXANE®, REVLIMID® and VIDAZA®, and 101% growth vs. the fourth quarter of 2017, the first full quarter following the license of these products from Celgene.

- Continued to expand potential patient access to ABRAXANE® (nanoparticle albumin-bound paclitaxel) in China through inclusion in the provincial reimbursement drug list in Hunan and critical illness insurance in Shandong.

Corporate Developments

- Completed an initial public offering as a dual primary listing on the Main Board of the Hong Kong Stock Exchange and a global offering in which we raised approximately $903 million in gross proceeds;
- Appointed Vivian Bian as China Co-Commercial Head, with strategic focus on marketing, strategy, new product introductions and business model innovation; and
- Continued the construction of the Guangzhou biologics manufacturing facility with the state-of-the-art KuBio™ prefabricated biomanufacturing equipment delivered by General Electric. The first phase of the facility is expected to be completed and operational in 2019.

Second Quarter 2018 Financial Results

Cash, Cash Equivalents, Restricted Cash and Short-Term Investments were $1,401.22 million as of June 30, 2018, compared to $1,481.48 million as of March 31, 2018 and $837.52 million at December 31, 2017. Cash, cash equivalents, restricted cash and short-term investments as of June 30, 2018 include approximately $145.28 million held by our 95%-owned joint venture, BeiGene Biologics, to build a commercial biologics manufacturing facility under construction in Guangzhou, China, and restricted cash of $31.59 million related to BeiGene Biologics' secured deposits. In the quarter, BeiGene Biologics received $42.32 million in proceeds from a new long-term loan with China Construction Bank for the continued construction of the manufacturing facility.

Cash used by operations for the three months ended June 30, 2018 was $117.14 million, compared to $51.89 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. Capital expenditures for the three months ended June 30, 2018 were $10.61 million, compared to $13.62 million for the same period in 2017. The decrease was primarily attributable to the purchase in the prior year period of the land use right in Guangzhou.

Revenue for the three months ended June 30, 2018 were $52.80 million, compared to nil in the same period in 2017, primarily attributable to product and collaboration revenue under our collaboration with Celgene.

- Product revenue from sales of ABRAXANE®, REVLIMID® and VIDAZA® in China totaled $31.43 million for the second quarter of 2018.
- Collaboration revenue totaled $21.38 million for the second quarter of 2018, reflecting $18.18 million of research and development reimbursement revenue from Celgene, $1.70 million of research and development service revenue from deferred recognition of upfront fees, and $1.50 million of milestone revenue under the collaboration agreement for pamiparib with Merck KGaA, Darmstadt, Germany.

Expenses for the three months ended June 30, 2018 were $215.85 million, compared to $58.02 million in the same period in 2017, consisting primarily of the following:

- **Cost of sales** for the three months ended June 30, 2018 were $6.26 million, compared to nil in the second quarter of 2017. 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 June 30, 2018 were $164.25 million, compared to $47.25 million in the same period in 2017. 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 compensation expense, which was $10.72 million for the three months ended June 30, 2018, compared to $4.75 million for the same period in 2017, due to increased headcount and a higher share price.

- **SG&A Expenses** for the three months ended June 30, 2018 were $45.16 million, compared to $10.78 million in the same period in 2017. 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-associated share-based compensation expense which was $7.92 million for the three months ended June 30, 2018, compared to $2.33 million for the same period in 2017, due to increased headcount and a higher share price.

- **Net Loss** for the second quarter of 2018 was $156.89 million, or $2.92 per American Depositary Share (ADS), compared to a net loss of $60.55 million, or $1.52 per ADS in the same period in 2017. For the second quarter of 2018, net loss per ordinary share was $0.22, compared to $0.12 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	
	June 30,	December 31,

	2018 (unaudited)	2017 (audited)
Cash, cash equivalents, restricted cash and short-term investments	$ 1,401,219	$ 837,516
Accounts receivable	33,171	29,428
Unbilled receivables	12,702	—
Working capital	1,330,272	763,509
Property and equipment, net	90,510	62,568
Total assets	1,653,856	1,046,479
Accounts payable	85,878	69,779
Accrued expenses and other payables	75,037	49,598
Bank loan [1]	60,534	18,444
Shareholder loan [1]	149,217	146,271
Total liabilities	427,188	362,248
Noncontrolling interest	13,471	14,422
Total equity	$ 1,226,668	$ 684,231

[1] The bank loan and shareholder loan balances attributable to BeiGene Biologics, a joint venture that is 95% owned by BeiGene, Ltd, totaled $42.40 million and $149.22 million, respectively, as of June 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue				
Product revenue, net	$ 31,426	$ —	$ 54,676	$ —
Collaboration revenue	21,378	—	30,672	—
Total revenues	52,804	—	85,348	—
Expenses:				
Cost of sales – products	(6,256)	—	(10,806)	—
Research and development	(164,251)	(47,245)	(273,951)	(90,018)
Selling, general and administrative	(45,160)	(10,777)	(74,075)	(19,546)
Amortization of intangible assets	(187)	—	(375)	—
Total expenses	(215,854)	(58,022)	(359,207)	(109,564)
Loss from operations	(163,050)	(58,022)	(273,859)	(109,564)
Interest income (expense), net	1,892	(1,982)	3,444	(1,796)
Other income (expense), net	75	(475)	804	438
Loss before income taxes	(161,083)	(60,479)	(269,611)	(110,922)
Income tax (expense) benefit	3,368	(201)	6,780	(381)
Net loss	$ (157,715)	$ (60,680)	$ (262,831)	$ (111,303)
Less: Net loss attributable to noncontrolling interest	(828)	(135)	(1,348)	(135)
Net loss attributable to BeiGene, Ltd.	$ (156,887)	$ (60,545)	$ (261,483)	$ (111,168)
Net loss attributable to BeiGene, Ltd. per ADS, basic and diluted	$ (2.92)	$ (1.52)	$ (4.97)	$ (2.80)
Weighted-average ADSs outstanding, basic and diluted	53,731,299	39,820,287	52,660,468	39,773,393
Net loss per share attributable to BeiGene, Ltd. basic and diluted	(0.22)	(0.12)	(0.38)	(0.22)

Weighted-average ordinary shares outstanding, basic and diluted	698,506,891	517,663,736	684,586,086	517,054,109

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	$ (157,715)	$ (60,680)	$ (262,831)	$ (111,303)
Other comprehensive loss, net of tax of nil:				
Foreign currency translation adjustments	2,033	554	2,305	644
Unrealized holding gain, net	719	19	1,048	7
Comprehensive loss	(154,963)	(60,107)	(259,478)	(110,652)
Less: Comprehensive loss attributable to noncontrolling interests	(870)	(108)	(1,326)	(108)
Comprehensive loss	$ (154,093)	$ (59,999)	$ (258,152)	$ (110,544)

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 1,300 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 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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