BeiGene

BeiGene Reports Fourth Quarter and Full Year 2018 Financial Results

Company to Host Annual Results Conference Call Today at 6:00 p.m. EST

and Investor Event in Hong Kong on February 28th at 2:30 p.m. HKT

CAMBRIDGE, Mass. and BEIJING, China, February 27, 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 fourth quarter and full year of 2018.

“Building on a strong foundation, in 2018 we took BeiGene to new heights with our first three new drug applications accepted and currently under priority review in China for zanubrutinib and tislelizumab,” said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. “In the United States, we received Breakthrough Therapy designation for zanubrutinib in patients with relapsed/refractory mantle cell lymphoma. We have become a global leader in China-inclusive global clinical development, supported by our internal clinical team of more than 800 people and a commitment to high quality standards.”

Oyler continued, “In 2019, we plan to continue to grow our commercial business, paving the way for our planned commercial launches in China this year and for our first new drug application in the United States planned for this year or in early 2020.”

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*

- Received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy;

- Granted priority review by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA, formerly known as CFDA) to new drug applications (NDAs) for the treatment of patients with relapsed or refractory (R/R) MCL and with R/R chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL);
- Presented 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;
- Presented updated data from a global Phase 1 trial in patients with MCL at the ASH Annual Meeting;
- Completed enrollment of a significantly expanded cohort 2, of 110 previously untreated patients with 17p deletion in the Phase 3 trial in first-line CLL/SLL; and
- Initiated a global Phase 2 trial in patients with R/R marginal zone lymphoma (MZL).

Expected Milestones for Zanubrutinib in 2019

- Receive approvals in China for the treatment of patients with R/R MCL and R/R CLL/SLL;
- Submit an initial 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;
- Announce top-line results from 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 CLL/SLL; Phase 1 obinutuzumab combination data in CLL/SLL; data from the MYD88WT cohort of the Phase 3 WM trial; 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

- Granted priority review by the CDE of NMPA to our NDA for the treatment of patients with R/R classical Hodgkin's lymphoma (cHL);
- Presented data from the pivotal Phase 2 trial of tislelizumab in Chinese patients with R/R cHL in an oral session at the ASH Annual Meeting;
- Presented updated data from Phase 1 trial expansion cohorts in patients with urothelial carcinoma, esophageal, gastric, hepatocellular, and non-small cell lung cancers at the European Society for Medical Oncology Immuno-Oncology (ESMO-IO) congress;
- Presented Phase 2 clinical results in esophageal squamous cell carcinoma (ESCC) and gastric cancer (GC) at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI);
- Completed enrollment of the global Phase 2 trial in second- or third-line patients with hepatocellular carcinoma (HCC); and
- Initiated the following clinical trials:
    - A global Phase 3 trial of tislelizumab in combination with chemotherapy in patients with front-line advanced gastric or gastroesophageal junction adenocarcinoma; and
    - A global Phase 3 trial of tislelizumab in combination with chemotherapy in patients with front-line, locally advanced recurrent or metastatic ESCC.

Expected Milestones for Tislelizumab in 2019

- Receive NDA approval in China for treatment of patients with R/R cHL;
- Announce top-line results from the pivotal Phase 2 trial in Chinese and Korean patients with PD-L1 positive urothelial bladder cancer (UBC) and submit an NDA in China for UBC;
- Announce top-line results from the global Phase 2 trial in second- or third-line patients with 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;

- Complete or close to completing enrollment in all four ongoing Phase 3 trials in lung and liver cancers; and
- Initiate additional pivotal solid tumor trials.

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

- Presented preliminary Phase 1/2 trial data of pamiparib in combination with radiation therapy and/or temozolomide in patients with newly diagnosed or R/R glioblastoma in an oral presentation at the 23rd Annual Scientific Meeting and Education Day of the Society for Neuro-Oncology (SNO); and
- Initiated a global Phase 2 trial in patients with metastatic castration-resistant prostate cancer (mCRPC) with homologous recombination deficiency (HRD).

Expected Milestones for Pamiparib 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 in patients with ovarian cancer from the global Phase 1 trial and updated Phase 1 combination data.

***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*

- Expanded Phase 1 combination trial with tislelizumab in China and Australia to a total of five advanced solid tumors including non-small cell lung cancer, renal cell carcinoma, ovarian cancer, HCC, and GC.

***BGB-A425,** an investigational TIM-3 antibody*

- Initiated a global Phase 1 trial in combination with tislelizumab.

Manufacturing

- Substantially completed physical construction of the commercial-scale biologics manufacturing facility in Guangzhou, China, with four 2,000 liter KUBio bioreactors installed.

Expected Milestone for Manufacturing in 2019

- Complete Phase 1 construction of the Guangzhou manufacturing facility, with expanded capacity to follow, to support the manufacturing of tislelizumab and other potential drug candidates in the pipeline.

Commercial Operations

- Generated $37.76 million and $130.89 million in product revenue in the fourth quarter and year ended December 31, 2018, respectively, from sales in China of ABRAXANE®, REVLIMID® and VIDAZA®, which represents a 142% increase and a 436% increase, respectively, compared to the same periods in 2017 (2017 revenue was from the last four months of the year after the Celgene transaction closed on August 31, 2017); and

- In support of the planned commercial launch of zanubrutinib in the United States, the Company made key hires in sales and marketing, market access, commercial operations, and business analytics. In China, the Company more than quadrupled the size of its commercial team since September 2017.

Corporate Developments

- Announced license and collaboration agreements with Zymeworks Inc., under which BeiGene acquired exclusive development and commercial rights in Asia-Pacific for Zymeworks' HER2-targeted therapeutic candidates ZW25 and ZW49, and a research and license agreement under which BeiGene acquired rights to internally develop and commercialize globally up to three other bispecific antibodies using Zymeworks' Azymetric™ and EFECT™ platforms; and

- Appointed Dr. Yong (Ben) Ben as Chief Medical Officer, Immuno-Oncology. Dr. Ben has extensive experience in immuno-oncology and early- to late-stage drug development, with multiple successful NDAs and biologics license applications (BLAs), including most recently the approval of PD-L1 immunotherapy IMFINZI® (durvalumab) for the treatment of certain patients with locally advanced or metastatic

urothelial cancer. Prior to joining BeiGene, he served most recently as chief medical officer of BioAtla, and previously worked at other pharmaceutical companies, including AstraZeneca, Millennium Pharmaceuticals, and Pfizer.

Fourth Quarter and Full Year 2018 Financial Results

Cash, Cash Equivalents, Restricted Cash and Short-Term Investments were $1.81 billion as of December 31, 2018, compared to $2.10 billion as of September 30, 2018 and $837.52 million as of December 31, 2017.

- The decrease of $291.85 million in the fourth quarter of 2018 was primarily due to $193.89 million of cash used in operating activities, a $60 million upfront payment made to Zymeworks under our collaboration agreement, $23.25 million for investments in property, plant and equipment, and the payment of the remaining $30.35 million acquisition cost for our research, development, and office facility in Changping, Beijing, China.

- The increase of $971.71 million from the prior year period was primarily due to net proceeds received from our global follow-on offering and initial listing on the Hong Kong Stock Exchange of $869.71 million in August 2018 and net proceeds from our follow-on offering on the NASDAQ of $757.59 million in January 2018. These net proceeds were partially offset by $547.72 million of cash used in operating activities, $70 million in upfront payments related to the Zymeworks and Mirati collaboration agreements, investments in property, plant and equipment totaling $70.28 million and primarily attributable to the build-out of our Guangzhou biologics manufacturing facility, and $38.30 million of total cost related to the acquisition of our Changping facility.

Revenue for the fourth quarter and year ended December 31, 2018 was $58.67 million and $198.22 million, respectively, compared to $18.17 million and $238.39 million in the same periods in 2017. The increase in the quarter-over-quarter period is attributable to increased product revenue in China and collaboration revenue under our license and collaboration agreements with Celgene. The decrease in the year-over-year period is due to the upfront

payment recognized in 2017 under our collaboration agreement with Celgene for tislelizumab.

- Product revenue from sales of ABRAXANE®, REVLIMID® and VIDAZA® in China totaled $37.76 million and $130.89 million for the fourth quarter and year ended December 31, 2018, respectively, compared to $15.61 million and $24.43 million for the same periods in 2017 (2017 revenue was from the last four months of the year after the Celgene transaction closed on August 31, 2017).

- Collaboration revenue totaled $20.91 million and $67.34 million for the fourth quarter and year ended December 31, 2018, respectively, compared to $2.57 million and $213.96 million for the same periods in 2017.

Expenses for the fourth quarter and year ended December 31, 2018 were $339.48 million and $903.99 million, respectively, compared to $121.97 million and $336.84 million in the same periods in 2017.

- **Cost of sales** for the fourth quarter and year ended December 31, 2018 were $9.19 million and $28.71 million, respectively, compared to $3.03 million and $4.97 million in the same periods in 2017 (the full year period in 2017 included only the last four months of the year after the Celgene deal closed on August 31, 2017). Cost of sales related to the cost of acquiring ABRAXANE®, REVLIMID® and VIDAZA® for distribution in China.

- **R&D Expenses** for the fourth quarter and year ended December 31, 2018 were $257.46 million and $679.01 million, respectively, compared to $91.34 million and $269.02 million in the same periods 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 submissions 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. Also contributing to the fourth quarter and year-over-year increases were expenses for in-process research and development collaborations, which totaled $79 million in the fourth quarter of 2018 (including $60 million related to the

Zymeworks collaboration and $19 million related to the termination of the Merck pamiparib collaboration) and $89 million (inclusive of the $10 million related to the Mirati collaboration) for the year ended December 31, 2018. We did not have any in-process research and development expense from collaborations in the fourth quarter or year ended December 31, 2017. Employee share-based compensation expense also contributed to the overall increase in R&D expenses, and was $16.09 million and $54.38 million for the fourth quarter and year ended December 31, 2018, respectively, compared to $10.95 million and $30.61 million for the same periods in 2017, due to increased headcount and a higher share price.

- **SG&A Expenses** for the fourth quarter and year ended December 31, 2018 were $72.49 million and $195.39 million, respectively, compared to $27.42 million and $62.60 million in the same periods 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 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 $9.87 million and $32.74 million for the fourth quarter and year ended December 31, 2018, respectively, compared to $5.51 million and $12.25 million for the same periods in 2017, due to increased headcount and a higher share price.

- **Net Loss** for the fourth quarter and year ended December 31, 2018 was $268.26 million and $673.77 million, or $0.35 and $0.93 per share, or $4.52 and $12.15 per American Depositary Share (ADS), respectively, compared to $99.32 million and $93.11 million, or $0.17 and $0.17 per share, or $2.19 and $2.23 per ADS, respectively, in the same periods in 2017.

Conference Call and Investor Event

The Company will hold a live webcast and conference call of fourth quarter and full year 2018 financial results, and business updates and

expected upcoming milestones, at 6:00 p.m. EST on February 27 (7:00 a.m. HKT on February 28.) The conference call will be conducted in English, and can be accessed by dialing +1 (844) 461-9930 or +1 (478) 219-0535 in the U.S.; +852 3011-4522 in Hong Kong; or +86 400-682-8609 in mainland China. Please dial in five minutes prior to the start time and provide the passcode 8889396.

In addition, the Company will host an investor and analyst event in Hong Kong from 2:30 p.m. to 4:00 p.m. HKT on February 28 (Thursday, February 28, at 1:30 a.m. EST). This event will be conducted primarily in Mandarin Chinese.

Both events will have live webcast and can be accessed by visiting the investor relations section of the BeiGene website at http://ir.beigene.com and/or http://hkexir.beigene.com. The replay of both events will be available on the BeiGene website approximately two hours following completion of the events and will be archived for three weeks.

Financial Summary

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

(Amounts in thousands of U.S. Dollars)

(Audited)

	As of	
	December 31, 2018	**December 31, 2017**
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 1,809,222	$ 837,516
Accounts receivable	41,056	29,428
Unbilled receivables	8,612	—
Working capital	1,697,390	763,509
Property and equipment, net	157,061	62,568
Total assets	2,249,684	1,046,479
Liabilities and equity:		
Accounts payable	113,283	69,779
Accrued expenses and other payables	100,414	49,598
Bank loan [1]	49,512	18,444
Shareholder loan [2]	148,888	146,271
Total liabilities	496,037	362,248
Noncontrolling interest	14,445	14,422
Total equity	$ 1,753,647	$ 684,231

[1] The bank loan is attributable to BeiGene Biologics, a joint venture that is 95% owned by BeiGene, Ltd, totaled $40.79 million as of December 31, 2018 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 from our joint venture partner for the construction and operation of our manufacturing facilities in Guangzhou.

BeiGene

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 December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
	(unaudited)		(audited)	
Revenue				
Product revenue, net	$ 37,762	$ 15,606	$ 130,885	$ 24,428
Collaboration revenue	20,908	2,568	67,335	213,959
Total revenues	58,670	18,174	198,220	238,387
Expenses:				
Cost of sales – products	(9,193)	(3,030)	(28,705)	(4,974)
Research and development [1]	(257,464)	(91,340)	(679,005)	(269,018)
Selling, general and administrative	(72,490)	(27,415)	(195,385)	(62,602)
Amortization of intangible assets	(331)	(187)	(894)	(250)
Total expenses	(339,478)	(121,972)	(903,989)	(336,844)
Loss from operations	(280,808)	(103,798)	(705,769)	(98,457)
Interest income (expense), net	5,950	(527)	13,947	(4,108)
Other (expense) income, net	(396)	9,960	1,993	11,501
Loss before income taxes	(275,254)	(94,365)	(689,829)	(91,064)
Income tax benefit (expense)	8,544	(4,915)	15,796	(2,235)
Net loss	(266,710)	(99,280)	(674,033)	(93,299)
Less: Net income (loss) attributable to noncontrolling interest	1,545	43	(264)	(194)
Net loss attributable to BeiGene, Ltd.	$ (268,255)	$ (99,323)	$ (673,769)	$ (93,105)
Net loss per share attributable to BeiGene, Ltd., basic and diluted	$ (0.35)	$ (0.17)	$ (0.93)	$ (0.17)
Weighted-average shares outstanding, basic and diluted	771,982,215	590,234,853	720,753,819	543,185,460
Net loss per ADS attributable to BeiGene, Ltd, basic and diluted	$ (4.52)	$ (2.19)	$ (12.15)	$ (2.23)
Weighted-average ADSs outstanding, basic and diluted	59,383,247	45,402,681	55,442,601	41,783,497

[1] Research and development expense for the fourth quarter and year ended December 31, 2018 includes expenses related to in-process research and development collaborations totaling $79 million and $89 million, respectively.

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 2,200 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 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.

Investor Contact
Craig West
+1 857-302-5189
ir@beigene.com

Media Contact
Liza Heapes
+ 1 857-302-5663
media@beigene.com

[i] ABRAXANE®, REVLIMID®, and VIDAZA® are registered trademarks of Celgene Corporation.