



# BeiGene

*Source: BeiGene, LTD.*

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## BeiGene Reports Second Quarter 2019 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, Aug. 08, 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 second quarter and first half of 2019.

“This quarter, our team continued to deliver across all functions, with the completion of enrollment in five Phase 3 or pivotal trials and the initiation of three new Phase 3 trials in oncology indications where we expect to have a profound impact on people fighting both hematologic and solid tumors. We believe that we are well-positioned to continue running our late-stage trials, including those for tislelizumab, for which we re-acquired full global rights from Celgene in advance of the closing of its pending acquisition by Bristol-Myers Squibb,” said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. “We are progressing well with our U.S. and China product launch preparations, including our commercial and manufacturing build-outs, and we expect the remainder of 2019 and 2020 to be transformative for BeiGene, with readouts from up to 10 ongoing Phase 3 or potentially registration-enabling studies in addition to planned commercial launches of two of our internally developed products.”

### 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*

- Completed enrollment in the global Phase 3 SEQUOIA trial (NCT03336333) comparing zanubrutinib with bendamustine plus rituximab in patients with treatment-naïve (TN) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL);
- Achieved first patient dosing in a Phase 1b trial (NCT02914938) conducted by MEI Pharma of zanubrutinib in combination with ME-401, an investigational selective oral phosphatidylinositol 3-kinase (PI3K) delta inhibitor;
- Presented data at the 15<sup>th</sup> International Conference on Malignant Lymphoma (ICML), including:
  - Clinical data from the pivotal Phase 2 trial (NCT03206918) in China in patients with relapsed/refractory (R/R) CLL or SLL;
  - Updated data from the pivotal Phase 2 trial (NCT03206970) in China in patients with R/R mantle cell lymphoma (MCL);
  - Updated data from the global Phase 1/2 trial (NCT02343120) in patients with different subtypes of B-cell malignancies, including MCL;
  - Updated data from the Phase 1b combination trial (NCT02569476) with GAZYVA<sup>®</sup> (obinutuzumab) in patients with R/R or TN CLL or SLL, and patients with R/R follicular lymphoma (FL).
- Presented data at the 24<sup>th</sup> Congress of European Hematology Association (EHA), including:
  - Clinical data from the nonrandomized cohort in patients with MYD88<sup>wt</sup> Waldenström's

Macroglobulinemia (WM) from the Phase 3 ASPEN trial (NCT03053440). The randomized cohort of the study, in patients with MYD88<sup>mut</sup> WM, is ongoing;

- Updated results from the ongoing Phase 1 trial (NCT02343120) of patients with WM;
- Pooled safety data from six ongoing monotherapy studies in patients with B-cell malignancies; and
- Published in *Blood*, the Journal of the American Society of Hematology, an article on the Phase 1 trial of zanubrutinib in R/R B-cell malignancies, including CLL/SLL.

#### *Expected Milestones for Zanubrutinib*

- Receive approvals in China for the treatment of patients with R/R MCL and R/R CLL/SLL in the first half of 2020. The Company expects manufacturing inspections to occur after the completion of the technical reviews. In addition, non-clinical and chemistry, manufacturing and controls (CMC) supplemental information was requested and has been provided;
- File an initial New Drug Application (NDA) in the U.S. in 2019 or early 2020;
- File a supplemental new drug application (sNDA) in China for WM in 2019;
- Announce top-line results from the Phase 3 ASPEN trial comparing zanubrutinib to ibrutinib in patients with WM in 2019;
- Announce top-line interim analysis from the SEQUOIA trial comparing zanubrutinib with bendamustine plus rituximab in patients with TN CLL or SLL as early as 2020; and
- Initiate a global Phase 3 clinical trial (NCT04002297) comparing zanubrutinib plus rituximab versus bendamustine plus rituximab in patients with previously untreated MCL who are ineligible for stem cell transplant in 2019.

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

- Filed an sNDA in China for patients with previously treated locally-advanced or metastatic urothelial carcinoma (UC); the sNDA has been granted priority review status from the China National Medical Products Administration (NMPA);
- Regained full global rights from Celgene in advance of its pending acquisition by Bristol-Myers Squibb, and received a payment of \$150 million in connection with the termination;
- Completed enrollment in the Phase 3 trials in China of tislelizumab combined with chemotherapy in the front-line setting for patients with advanced squamous (NCT03594747) and non-squamous (NCT03663205) non-small cell lung cancer (NSCLC);
- Initiated the following trials:
  - A Phase 3 randomized trial (NCT04005716) in China of platinum plus etoposide with or without tislelizumab in patients with untreated extensive-stage small cell lung cancer (SCLC);
  - A Phase 3 randomized trial (NCT03967977) in China of tislelizumab in combination with chemotherapy versus chemotherapy alone in patients with previously untreated locally advanced or metastatic UC; and
  - A Phase 3 randomized trial (NCT03957590) in China of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized esophageal squamous cell carcinoma (ESCC).
- Presented updated clinical results from the pivotal Phase 2 trial (NCT03209973) in China in patients with R/R classical Hodgkin lymphoma (cHL) at EHA; and
- Presented preliminary Phase 2 results from the Phase 1/2 trial (NCT03924986) in China in patients with nasopharyngeal cancer (NPC) at ASCO.

#### *Expected Milestones for Tislelizumab*

- Receive NDA approval in China for treatment of patients with R/R cHL in 2019;
- Announce top-line results from the global Phase 2 trial (NCT03419897) in second- or third-line patients with hepatocellular carcinoma (HCC) in 2019 or early 2020 and have regulatory discussions;
- Announce top-line results from the Phase 3 trial (NCT03594747) in first-line squamous NSCLC in China in 2019 or 2020;
- Announce top-line results from the Phase 3 trial (NCT03663205) in first-line non-squamous NSCLC in China in 2020; and
- Complete enrollment in the global first-line Phase 3 trial (NCT03412773) in HCC in 2019 and the global portion of the second-line Phase 3 trial (NCT03358875) in NSCLC in 2019 or early 2020.

***Pamiparib, an investigational small molecule PARP inhibitor***

- Completed enrollment in the Phase 3 randomized trial in China (NCT03519230) of pamiparib versus placebo as a potential maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer;
- Completed enrollment in the pivotal Phase 2 trial in China (NCT03333915) in third-line and above patients with ovarian cancer with germ-line BRCA mutation; and
- Published in *The Lancet Oncology* an article on the Phase 1A/B trial of pamiparib in combination with tislelizumab in patients with advanced solid tumors.

***Expected Milestones for Pamiparib***

- Announce top-line results from the pivotal Phase 2 trial in Chinese patients with previously treated ovarian cancer in 2020; and
- Announce top-line results from the Phase 3 trial in China of pamiparib versus placebo as a potential maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer in 2020.

***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 1/2 trial (NCT03941873) in China of sitravatinib in combination with tislelizumab in patients with unresectable locally advanced or metastatic HCC or gastroesophageal junction cancer.

***BGB-A1217, an investigational TIGIT monoclonal antibody discovered by BeiGene scientists***

***Expected Milestones for BGB-A1217***

- Initiate patient enrollment in a Phase 1a/1b trial 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 in 2019.

**Manufacturing Facilities**

- Completed equipment installation and systems qualification of the Company's biologics manufacturing facility in Guangzhou, China. We expect manufacturing and validation of tislelizumab drug substance to begin later this year.

**Commercial Product Portfolio**

- Generated \$58.14 million in product revenue in the three months ended June 30, 2019, from sales in China of ABRAXANE<sup>®</sup>, REVLIMID<sup>®</sup> and VIDAZA<sup>®</sup>, which represents an 85.0% increase compared to the same period in 2018; and
- Announced that the China National Medical Products Administration (NMPA, formerly known as CFDA) accepted the supplemental import drug application for ABRAXANE<sup>®</sup> (paclitaxel protein-bound particles for injectable suspension) (albumin-bound), in combination with gemcitabine, as a potential first-line treatment of patients with metastatic adenocarcinoma of the pancreas (mPC).

**Corporate Developments**

- Received approval from the Stock Exchange of Hong Kong Limited (HKEX) to transition into a general listing under Rule 8.05(3) by meeting its specified revenue and market capitalization thresholds. As a result of the approval, the “B” marker was removed from the Company’s stock symbol in the HKEX, and the Company’s ordinary shares may become eligible for listing in the Hang Seng indices;
- Along with SpringWorks Therapeutics, announced the formation of MapKure, LLC to develop BGB-3245, an investigational, selective next-generation RAF kinase inhibitor discovered by BeiGene scientists;
- Appointed Qingyi “Anita” Wu as Chief Commercial Officer, Greater China. Prior to joining BeiGene, Anita served as General Manager of the Specialty Care business unit at Sanofi China; and
- Appointed Yan “Lily” Liu as Vice President, Head of Marketing, Greater China. Lily was most recently Vice President, Head of the Specialty Care business unit at Takeda China.

## **Second Quarter 2019 Financial Results**

**Cash, Cash Equivalents, Restricted Cash and Short-Term Investments** were \$1.56 billion as of June 30, 2019, compared to \$1.64 billion as of March 31, 2019 and \$1.81 billion as of December 31, 2018.

- The decrease of \$76.07 million in the second quarter of 2019 was primarily due to \$46.10 million of cash used in operating activities, \$21.45 million for investments in property, plant and equipment, and \$20 million for an upfront payment related to the BioAtla collaboration agreement.

**Revenue** for the quarter ended June 30, 2019 was \$243.35 million, compared to \$52.80 million in the same period in 2018. The increase is primarily attributable to the \$150 million payment received in connection with the termination of the tislelizumab collaboration agreement with Celgene, the recognition of previously deferred revenue from the collaboration as well as increased product revenue from sales of the in-licensed products from Celgene in China.

- Product revenue from sales of ABRAXANE<sup>®</sup>, REVLIMID<sup>®</sup> and VIDAZA<sup>®</sup> in China totaled \$58.14 million for the second quarter ended June 30, 2019, compared to \$31.43 million for the same period in 2018.
- Collaboration revenue totaled \$185.20 million for the second quarter ended June 30, 2019, compared to \$21.38 million for the same period in 2018. The increase is due primarily to the \$150 million payment in connection with the termination of our tislelizumab collaboration agreement with Celgene, as well as the recognition of previously deferred revenue from the collaboration.

**Expenses** for the second quarter ended June 30, 2019 were \$329.18 million, compared to \$215.85 million in the same period in 2018.

- **Cost of sales** for the second quarter ended June 30, 2019 were \$17.84 million, compared to \$6.26 million in the same period in 2018. Cost of sales related to the cost of acquiring ABRAXANE<sup>®</sup>, REVLIMID<sup>®</sup> and VIDAZA<sup>®</sup> for distribution in China.
- **R&D Expenses** for the second quarter ended June 30, 2019 were \$228.76 million, compared to \$164.25 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. Additionally, we expensed \$20.0 million for the upfront payment related to the BioAtla collaboration agreement. Employee share-based compensation expense also contributed to the overall increase in R&D expenses, and was \$18.15 million for the second quarter ended June 30, 2019, compared to \$10.72 million for the same period in 2018, due to increased headcount.
- **SG&A Expenses** for the second quarter ended June 30, 2019 were \$82.25 million, compared to \$45.16 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 \$14.45 million for the second quarter ended June 30, 2019, compared to \$7.92 million for the same period in 2018, due to increased headcount.
- **Net Loss** for the second quarter ended June 30, 2019 was \$85.57 million, or \$0.11 per share, or \$1.43 per American Depositary Share (ADS), compared to \$156.89 million, or \$0.22 per share, or \$2.92 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	
	June 30, 2019	December 31, 2018
	(unaudited)	(audited)
<b>Assets:</b>		
Cash, cash equivalents, restricted cash and short-term investments	\$ 1,561,479	\$ 1,809,222
Accounts receivable	58,108	41,056
Working capital	1,484,001	1,697,390
Property and equipment, net	212,672	157,061
Total assets	2,150,318	2,249,684
<b>Liabilities and equity:</b>		
Accounts payable	148,536	113,283
Accrued expenses and other payables	103,061	100,414
Bank loan [1]	93,229	49,512
Shareholder loan [2]	154,321	148,888
Total liabilities	579,054	496,037
Noncontrolling interest	17,387	14,445
Total equity	\$ 1,571,264	\$ 1,753,647

[1] The bank loan is attributable to BeiGene Biologics, a joint venture that is 95% owned by BeiGene, Ltd., which totaled \$84.49 million as of June 30, 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 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(unaudited)			
<b>Revenue:</b>				
Product revenue, net	\$ 58,142	\$ 31,426	\$ 115,563	\$ 54,676
Collaboration revenue	185,204	21,378	205,616	30,672
Total revenues	243,346	52,804	321,179	85,348
<b>Expenses:</b>				
Cost of sales - products	(17,839)	(6,256)	(33,100)	(10,806)
Research and development	(228,760)	(164,251)	(407,111)	(273,951)
Selling, general and administrative	(82,248)	(45,160)	(139,893)	(74,075)
Amortization of intangible assets	(332)	(187)	(663)	(375)
Total expenses	(329,179)	(215,854)	(580,767)	(359,207)
Loss from operations	(85,833)	(163,050)	(259,588)	(273,859)
Interest income, net	2,886	1,892	7,363	3,444
Other (expense) income, net	(878)	75	850	804
Loss before income taxes	(83,825)	(161,083)	(251,375)	(269,611)

Income tax (expense) benefit	(2,129)	3,368	(2,648)	6,780
Net loss	(85,954)	(157,715)	(254,023)	(262,831)
Less: Net loss attributable to noncontrolling interest	(384)	(828)	(813)	(1,348)
Net loss attributable to BeiGene, Ltd.	<u>\$ (85,570)</u>	<u>\$ (156,887)</u>	<u>\$ (253,210)</u>	<u>\$ (261,483)</u>
Net loss per share attributable to BeiGene, Ltd., basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.22)</u>	<u>\$ (0.33)</u>	<u>\$ (0.38)</u>
Weighted-average shares outstanding, basic and diluted	<u>777,509,102</u>	<u>698,506,891</u>	<u>776,137,299</u>	<u>684,586,086</u>
Net loss per ADS attributable to BeiGene, Ltd., basic and diluted	<u>\$ (1.43)</u>	<u>\$ (2.92)</u>	<u>\$ (4.24)</u>	<u>\$ (4.97)</u>
Weighted-average ADSs outstanding, basic and diluted	<u>59,808,392</u>	<u>53,731,299</u>	<u>59,702,869</u>	<u>52,660,468</u>

## 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 2,700 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<sup>®</sup> (nanoparticle albumin-bound paclitaxel), REVLIMID<sup>®</sup> (lenalidomide), and VIDAZA<sup>®</sup> (azacitidine) in China under a license from Celgene Corporation<sup>i</sup>.

## 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 conduct of late-stage clinical trials and expected data readouts; the potential 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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