Source : *BeiGene, LTD.*

11 mai 2020 16h05 HE

BeiGene Reports First Quarter 2020 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, May 11, 2020 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology 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 2020.

“Our recent approval of tislelizumab in China for patients with previously treated locally advanced or metastatic urothelial carcinoma, as well as the positive readouts of two Phase 3 trials of tislelizumab for first-line non-small cell lung cancer at interim analyses, are key milestones for BeiGene as we execute on our goals and work to create impactful medicines that will be accessible to far more cancer patients around the world. With the COVID-19 pandemic continuing to create obstacles globally, our team has been quick to react as we work to minimize the impact and support our patients and physicians on the frontlines. We are managing the challenges to maintain momentum with our broad development program and are contributing to the global effort to fight the pandemic,” said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. “In addition to our launch of tislelizumab in China this quarter, we are on the way to having potentially up to 11 commercial products before the end of next year, and look forward to presenting Phase 3 data on BRUKINSA™ and tislelizumab at ASCO. We also anticipate several additional Phase 3 or potentially registration-enabling studies reading out in the next 12 months.”

Recent Business Highlights and Upcoming Milestones

Commercial Operations

- Launched tislelizumab in China in March 2020 for patients with classical Hodgkin’s lymphoma (cHL) who have received at least two prior therapies;
- Received approval from the China National Medical Products Administration (NMPA) for tislelizumab as a treatment for patients with previously treated locally advanced or metastatic urothelial carcinoma;
- Generated $52.06 million in product revenue in the three months ended March 31, 2020;
- As announced previously, the NMPA suspended the importation, sales and use of ABRAXANE® (nanoparticle albumin-bound paclitaxel) in China supplied to BeiGene by Celgene Corporation, a Bristol Myers Squibb (BMS) company. As a result, Celgene initiated a voluntary recall of ABRAXANE in mainland China; and
- Received commercial insurance reimbursement for tislelizumab as a treatment for relapsed/refractory classical Hodgkin's lymphoma in Zhuhai, China.

Amgen Collaboration

- Transition activities for the three Amgen commercial oncology medicines, XGEVA® (denosumab), KYPROLIS® (carfilzomib), and BLINCYTO® (blinatumomab) in China are on track. BeiGene is preparing to commence promotional activities for XGEVA in patients with giant cell tumor of bone in the third quarter of 2020. Regulatory activities for KYPROLIS and BLINCYTO are in progress, with new drug applications (NDAs) to the NMPA submitted in the fourth quarter 2019. Additionally, a supplemental NDA for XGEVA for an expanded indication in skeletal-related events in China was accepted by the NMPA; and
- BeiGene is working with Amgen to advance the clinical-stage oncology assets in the collaboration pursuant to the global development plan.

EUSA Collaboration

- Regulatory discussions are in progress and biologics license applications (BLAs) in China for both SYLVANT® (siltuximab) and QARZIBA®▼ (dinutuximab beta) are expected to be submitted in 2020.

Clinical Programs

BRUKINSA™ (zanubrutinib), *a small molecule inhibitor of Bruton's tyrosine kinase (BTK) designed to maximize BTK occupancy and minimize off-target effects; approved in the United States*

- Initiated a multi-center Phase 2 clinical trial (NCT04382586) evaluating zanubrutinib for the treatment of patients hospitalized for COVID-19 infection and pulmonary distress. The trial is designed to enroll approximately 42 patients, randomized to receive oral zanubrutinib at 320 mg once daily for 28 days plus supportive care, or placebo plus supportive care. An additional cohort of four to 10 patients on mechanical ventilation will all receive zanubrutinib plus supportive care. The trial's primary endpoint is the respiratory failure-free survival rate at day 28 in the randomized cohort.

Expected Milestones for Zanubrutinib

- Receive approvals in China for the treatment of patients with relapsed/refractory (R/R) mantle cell lymphoma (MCL) and R/R chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in the first half of 2020;

- Announce top-line results from the SEQUOIA trial comparing zanubrutinib with bendamustine plus rituximab in patients with treatment-naïve CLL or SLL as early as the second half of 2020;

- File a supplemental new drug application (sNDA) in China for Waldenström's macroglobulinemia (WM) in 2020;

- Discuss data from the Phase 3 ASPEN trial (NCT03053440) comparing zanubrutinib to ibrutinib in patients with WM with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) in 2020;

- Complete expanded enrollment in the Phase 3 ALPINE trial (NCT03734016) comparing zanubrutinib with ibrutinib in patients with R/R CLL/SLL in 2020; and

- Present data from Phase 3 ASPEN trial comparing zanubrutinib to ibrutinib in patients with WM in an oral presentation at the 2020 ASCO Virtual Science Program being held May 29-31, 2020, and present three-year follow-up data of treatment-naïve and previously treated patients with WM.

Tislelizumab*, a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages; approved in China*

- Announced that the Center for Drug Evaluation (CDE) of the NMPA accepted an sNDA of tislelizumab in combination with two chemotherapy regimens for first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC);

- Announced that the pivotal Phase 3 trial (NCT03663205) of patients with first-line advanced non-squamous NSCLC met its primary endpoint at the planned interim analysis, demonstrating a statistically significant improvement in progression-free survival (PFS) for tislelizumab in combination with pemetrexed and platinum chemotherapy compared to pemetrexed and platinum chemotherapy alone as assessed by the independent review committee (IRC). The safety profile of tislelizumab in combination with pemetrexed and platinum chemotherapy was consistent with the known risks of each study treatment, and no new safety signals were identified;

- Completed enrollment in the Phase 3 trial (NCT03358875) of tislelizumab versus docetaxel as a second- or third-line treatment in patients with NSCLC; and

- Completed enrollment in the global Phase 3 trial (NCT03430843) of tislelizumab versus chemotherapy as a second-line treatment in patients with advanced esophageal squamous cell carcinoma (ESCC).

Expected Milestones for Tislelizumab

- Submit an sNDA in China for first-line treatment of patients with advanced non-squamous NSCLC in 2020 and present data at an upcoming medical conference;

- Have regulatory discussions with health authorities based on preliminary results from the global Phase 2 trial (NCT03419897) in second- or third-line patients with hepatocellular carcinoma (HCC) in 2020;
- Present data from the Phase 3 trial in patients with first-line advanced squamous NSCLC at the 2020 ASCO Virtual Scientific Program;
- Announce top-line results from the Phase 3 trial (NCT03358875) comparing tislelizumab versus docetaxel in second-or third-line patients with NSCLC and in the global Phase 3 trial (NCT03430843) comparing tislelizumab versus chemotherapy in second-line patients with advanced ESCC in 2020 or early 2021;
- Initiate a Phase 3 trial in China for patients with resectable Stage II or IIIA NSCLC; and
- Complete enrollment in the pivotal Phase 2 trial (NCT03736889) in China of patients with mismatched repair deficient (dMMR) or microsatellite instability-high (MSI-H) solid tumors in 2020.

***Pamiparib**, an investigational selective small molecule inhibitor of PARP1 and PARP2*

- Completed enrollment in the Phase 2 clinical trial (NCT03575065) in China in patients with advanced HER2-negative breast cancer harboring germline BRCA mutation that have progressed despite standard therapy or for which no standard therapy exists.

Expected Milestones for Pamiparib

- Have regulatory discussions based on preliminary results from the Phase 2 trial (NCT03333915) in Chinese patients with third-line and above previously treated ovarian cancer (OC) harboring germline BRCA 1/2 mutations, and potentially submit an NDA in China in 2020;
- Announce top-line results from the Phase 3 trial (NCT03519230) of pamiparib as a maintenance treatment in patients with platinum-sensitive recurrent OC in 2020 or the first half of 2021; and
- Present updated data from the Phase 1 trial (NCT02660034) of pamiparib in combination with tislelizumab in patients with advanced solid tumors in 2020.

***Lifirafenib**, an investigational RAF dimer inhibitor*

- Published Phase 1 data in the *Journal of Clinical Oncology*.

***BGB-A1217**, an investigational TIGIT monoclonal antibody*

Expected Milestones for BGB-A1217

- Present clinical data from the Phase 1 trial in 2020 or early 2021.

***BGB-11417**, an investigational small molecule Bcl-2 inhibitor*

- Initiated patient enrollment for the Phase 1 trial (NCT04277637) of BGB-11417 in patients with mature B-cell malignancies. We intend to develop BGB-11417 both as a monotherapy and in combination with zanubrutinib.

Collaboration Programs

***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 Milestones for Sitravatinib

- Present additional Phase 1 clinical data on sitravatinib combined with tislelizumab at a medical meeting in 2020.

***ZW25,** a novel investigational Azymetric™ bispecific antibody currently in Phase 2 clinical development with Zymeworks, Inc.*

- Initiated enrollment in a two-arm Phase 1b/2 trial (NCT04276493) evaluating ZW25 in combination with chemotherapy as a first-line treatment for patients with metastatic HER2-positive breast cancer and in combination with chemotherapy and tislelizumab as a first-line treatment for patients with metastatic HER2-positive gastroesophageal adenocarcinoma (GEA).

Expected Milestones for ZW25

- Support clinical development and enrollment of the planned registration-enabling trials in refractory HER2-positive biliary tract cancer in 2020 and first-line HER2-positive gastroesophageal adenocarcinomas in late 2020 or early 2021.

***BGB-3245**, an investigational RAF dimer inhibitor with activity against mutant monomeric and dimeric forms of B-RAF in preclinical studies. BGB-3245 is being developed by MapKure, which BeiGene jointly owns with SpringWorks Therapeutics*

- Announced that the first patient has been dosed in Australia in the Phase 1 clinical trial (NCT04249843) in patients with advanced or refractory solid tumors. The U.S. FDA has allowed the Investigational New Drug (IND) application submitted for BGB-3245 to proceed, which will enable study expansion to U.S. sites.

Manufacturing Facilities

- Completed equipment validation and executed manufacturing process validation for the first phase of our manufacturing facility in Guangzhou; and

- Began construction of the second phase of our manufacturing facility in Guangzhou to significantly increase manufacturing capacity, expected to be completed by the end of 2020.

COVID-19 Impact and Response

- The Company expects that the worldwide health crisis of COVID-19 will have a negative impact on its operations, including commercial sales, regulatory interactions and inspections, and clinical trial recruitment and participation. The impact on the Company's operations in China has started to alleviate, as much of the country gradually resumes regular business. The Company is working to continue to minimize delays and disruptions and continues to execute on its commercialization, regulatory and clinical development goals globally.

- In addition to the clinical trial of zanubrutinib in COVID-19 patients, the Company announced plans to work with Atreca, Inc. and IGM Biosciences, Inc. to leverage the parties' technology and expertise in an effort to discover, develop, and manufacture novel IgM or IgA antibodies targeting SARS-CoV-2 for the potential treatment of COVID-19.

First Quarter 2020 Financial Results

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were $3.38 billion as of March 31, 2020, compared to $985.50 million as of December 31, 2019.

- Total cash and short-term investments increased $2.39 billion in the three months ended March 31, 2020, primarily due to the $2.78 billion of cash received from the sale of American Depositary Shares to Amgen in connection with the closing of the Amgen collaboration on January 2, 2020. In the three months ended March 31, 2020, cash used in operating activities totaled $341.94 million, capital expenditures were $21.53 million, and cash used for upfront license payments totaled $43.00 million.

Revenue for the three months ended March 31, 2020 was $52.06 million, compared to $77.83 million in the same period of 2019. The decrease in total revenue is primarily attributable to the lack of collaboration revenue after the termination of the Celgene collaboration agreement for tislelizumab and decreased product sales of ABRAXANE, REVLIMID® (lenalidomide) and VIDAZA® (azacitidine) in China, partially offset by the initial sales of tislelizumab in China and BRUKINSA in the United States.

- Product revenues totaled $52.06 million for the three months ended March 31, 2020, compared to $57.42 million for the three months ended March 31, 2019, and were comprised of:

  - Product revenue of $20.53 million from sales of tislelizumab in China since its launch in March 2020, including launch inventory build at distributors. Despite the challenges posed by COVID-19, the China commercial team launched tislelizumab on plan in the first quarter through efforts in multiple channels including extensive online promotion;

  - Product revenue of $30.82 million from sales of ABRAXANE, REVLIMID and VIDAZA in China, compared to $57.42 million in the same period of the prior year. The decrease in revenues was due to the negative impact of the COVID-19 pandemic, increased generic competition, and the suspension of ABRAXANE sales in China by the NMPA in March 2020; and

- Product revenue of $0.72 million from sales of BRUKINSA in the United States. Early launch indicators including new patient starts, reimbursement coverage, and physician perception have been encouraging.

- Collaboration revenue totaled nil for the three months ended March 31, 2020, compared to $20.41 million for the three months ended March 31, 2019.

Expenses for the three months ended March 31, 2020 were $425.82 million, compared to $251.59 million in the same period of 2019.

- **Cost of sales** for the three months ended March 31, 2020 were $14.15 million, compared to $15.26 million in the same period of 2019. Cost of sales primarily includes acquisition costs related to the amount of ABRAXANE, REVLIMID and VIDAZA that was sold during the period in China, as well as the post-approval cost of tislelizumab and BRUKINSA that was sold during the period.

- **R&D Expenses** for the three months ended March 31, 2020 were $304.30 million, compared to $178.35 million in the same period of 2019. The increase in R&D expenses was primarily attributable to continued increases in spending on our ongoing and newly initiated late-stage pivotal clinical trials, development expenses associated with the Amgen collaboration, the preparation for additional regulatory submissions, and manufacturing costs related to pre-commercial activities and supply. R&D expense in the three months ended March 31, 2020 also included $43.00 million of expense related to upfront license payments, compared to $10.00 million in the same period of 2019. Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the three months ended March 31, 2020 was $56.00 million, of which $28.37 million was recorded as R&D expense. The remaining $27.63 million was recorded as a reduction of the R&D cost share liability. R&D-related share-based compensation expense was $20.40 million for the three months ended March 31, 2020, compared to $15.77 million for the same period of 2019.

- **SG&A Expenses** for the three months ended March 31, 2020 were $107.08 million, compared to $57.65 million in the same period in 2019. 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 United States, as well as higher professional service fees and costs to support our growing operations. SG&A-related share-based compensation expense was $17.86 million for the three months ended March 31, 2020, compared to $10.62 million for the same period of 2019.

- **Net Loss** for the three months ended March 31, 2020 was $363.74 million, or $0.36 per share, or $4.70 per American Depositary Share (ADS), compared to $167.64 million, or $0.22 per share, or $2.81 per ADS in the same period in 2019.

Financial Summary

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

(Amounts in thousands of U.S. Dollars)

	As of	
	March 31, 2020	December 31, 2019
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 3,376,915	$ 985,503
Accounts receivable, net	65,620	70,878
Working capital	3,143,390	862,384
Property and equipment, net	240,331	242,402
Total assets	4,067,212	1,612,289
Liabilities and equity:		
Accounts payable	98,364	122,488
Accrued expenses and other payables	179,331	163,556
Bank loan	81,913	83,311
Shareholder loan	157,278	157,384
Research and development cost share liability	589,200	—
Total liabilities	1,240,156	633,934

Noncontrolling interest	14,842	16,150
Total equity	$ 2,827,056	$ 978,355

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,	
	2020	2019
	(Unaudited)	
Revenue:		
Product revenue, net	$ 52,059	$ 57,421
Collaboration revenue	—	20,412
Total revenues	52,059	77,833
Expenses:		
Cost of sales - products	14,149	15,261
Research and development	304,302	178,351
Selling, general and administrative	107,081	57,645
Amortization of intangible assets	283	331
Total expenses	425,815	251,588
Loss from operations	(373,756)	(173,755)
Interest income, net	6,690	4,477
Other income, net	3,681	1,728
Loss before income taxes	(363,385)	(167,550)
Income tax expense	1,554	519
Net loss	(364,939)	(168,069)
Less: Net loss attributable to noncontrolling interest	(1,204)	(429)
Net loss attributable to BeiGene, Ltd.	$ (363,735)	$ (167,640)
Net loss per share attributable to BeiGene, Ltd., basic and diluted	$ (0.36)	$ (0.22)
Weighted-average shares outstanding, basic and diluted	1,005,347,581	774,750,255
Net loss per ADS attributable to BeiGene, Ltd., basic and diluted	$ (4.70)	$ (2.81)
Weighted-average ADSs outstanding, basic and diluted	77,334,429	59,596,173

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 3,800+ employees in China, the United States, Australia, and Europe are committed to expediting the development of a diverse pipeline of novel therapeutics for cancer. We currently market two internally-discovered oncology products: BTK inhibitor BRUKINSA™ (zanubrutinib) in the United States, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

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 recent clinical data for BeiGene's product candidates and approvals of its products; the conduct of late-stage clinical trials and expected data readouts; additional planned commercial product launches; the advancement of and anticipated clinical development, regulatory milestones and commercialization of BeiGene's products and drug candidates; the success of launch efforts for tislelizumab and BRUKINSA; BeiGene's efforts to minimize the impact of the COVID-19 pandemic on its operations and to support its patients and physicians on the frontlines; BeiGene's efforts to develop a therapeutic treatment for COVID-19; the impact of the COVID-19 pandemic on the

Company's clinical development, commercial and other operations; 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; the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, 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.

Investor Contact	Media Contact
Craig West	Liza Heapes or Vivian Ni
+1 857-302-5189	+1 857-302-7596
ir@beigene.com	media@beigene.com