Source: *BeiGene, LTD.*

March 02, 2020 16:05 ET

BeiGene Reports Fourth Quarter and Full Year 2019 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, March 02, 2020 (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 2019.

“Having co-founded BeiGene in 2010 with Dr. Xiaodong Wang, this anniversary year promises to continue the momentum and trajectory from our recent catalysts, including the read-outs of two Phase 3 trials, approvals for BRUKINSA and tislelizumab in the United States and China, respectively, and closing on our collaboration with Amgen, which is already off to a productive start as we advance the commercialization and development plans for Amgen’s three commercial-stage drugs and 20 drug candidates,” said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. “In the next two years, we expect to launch up to eight products and see continued robust clinical progress with the potential readout of more than 10 Phase 3 or potentially registration-enabling studies. Our earlier stage pipeline is also advancing with several internally developed or in-licensed drug candidates entering the clinic or reporting proof of concept data.”

“Despite challenges to our business in China caused by the coronavirus outbreak (COVID-19), our team has continued to advance our programs and serve our patients. BeiGene took immediate safety measures to protect our staff in Wuhan and elsewhere and our employees are safe. In addition, we were one of the first companies to source and deliver donated safety equipment to major hospitals in the area. While we expect our broad business operations in China to be impacted by COVID-19, we continue to execute towards our tislelizumab launch goal in the first quarter this year,” said Dr. Xiaobin Wu, General Manager of China and President of BeiGene.

Recent Business Highlights and Upcoming Milestones

Commercial Operations

- Received accelerated approval from the U.S. Food and Drug Administration (FDA) of BRUKINSA™ (zanubrutinib) as a treatment for mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy; and launched within one week of approval;

- Received approval from the China National Medical Products Administration (NMPA) of tislelizumab as a treatment for patients with classical Hodgkin’s lymphoma (cHL) who have received at least two prior therapies, with launch planned this month;

- Generated $222.60 million in product revenue in the 12 months ended December 31, 2019, primarily from sales in China of ABRAXANE®, REVLIMID®, and VIDAZA®, which represents a 70.1% increase compared to the same period in 2018. Revenue for the quarter ended December 31, 2019 was $56.89 million. BeiGene markets ABRAXANE, REVLIMID, and VIDAZA in China under an exclusive license from Celgene Logistics Sàrl, a Bristol-Myers Squibb company;

- Submitted to the NMPA a supplemental new drug application (sNDA) for REVLIMID (lenalidomide), in combination with rituximab, for the treatment of patients with relapsed or refractory (R/R) indolent lymphoma (follicular lymphoma or marginal zone lymphoma). The sNDA has been accepted and granted priority review; and

- ABRAXANE was included in the National Healthcare Security Administration of China’s volume-based procurement list, effective in the second quarter of 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*

- Announced results of the Phase 3 ASPEN trial (NCT03053440) comparing BRUKINSA to ibrutinib for the treatment of Waldenström's macroglobulinemia (WM). While the primary endpoint of statistical superiority related to deep response (VGPR or better) was not met, zanubrutinib demonstrated more frequent VGPRs (28.4% vs. 19.2% in overall population) and advantages in safety and tolerability compared to ibrutinib. ASPEN is the largest Phase 3 trial in WM conducted to-date and the first comparative trial readout for BTK inhibitors;

- Completed enrollment in the Phase 2 MAGNOLIA trial (NCT03846427) in patients with R/R marginal zone lymphoma (MZL);

- Presented clinical data on BRUKINSA at the 61st American Society of Hematology (ASH) Annual Meeting, including:

  -- Initial results presented in an oral session of the SEQUOIA trial (NCT03336333) Arm C in patients with treatment-naïve (TN) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) with Del(17p);

  -- Updated results presented in an oral session of the Phase 1/2 trial (NCT02343120) in patients with CLL or SLL;

  -- Updated results presented in a poster from the Phase 1b trial (NCT02795182) of BRUKINSA in combination with tislelizumab in patients with previously treated B-cell lymphoid malignancies; and

- Initiated a Phase 1/2 clinical trial in Japan of zanubrutinib in patients with mature B-cell malignancies.

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;

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

- File an sNDA in China for WM in 2020;

- Discuss ASPEN data with U.S. FDA and European Medicines Agency (EMA) and present Phase 3 ASPEN data at a major medical conference in 2020; and

- Complete expanded enrollment in the Phase 3 ALPINE trial comparing zanubrutinib with ibrutinib in patients with R/R CLL/SLL in 2020.

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

- Announced that the pivotal Phase 3 trial (NCT 03594747) of tislelizumab in combination with chemotherapy for the first-line treatment of patients with squamous non-small cell lung cancer (NSCLC) met the primary endpoint of improved progression-free survival (PFS) at the pre-planned interim analysis, as assessed by independent review committee (IRC). The safety profile of tislelizumab in both combinations in this trial was consistent with the known risks of each study treatment, and no new safety signals were identified;

- Received orphan-drug designation for tislelizumab from the U.S. FDA for hepatocellular carcinoma (HCC) and esophageal squamous cell carcinoma (ESCC); and

- Announced updated clinical results presented at the ESMO Asia 2019 Congress from the Phase 2 trial (NCT03469557) of tislelizumab in combination with chemotherapy in patients with gastric/gastroesophageal junction (G/GEJ) adenocarcinoma or ESCC.

Expected Milestones for Tislelizumab

- Receive approval in China for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) in 2020;

- Submit sNDA for the first-line treatment of patients with squamous NSCLC in China in 2020;

- Have regulatory discussions with health authorities based on preliminary results from the global Phase 2 trial (NCT03419897) of tislelizumab in second- or third-line patients with HCC in 2020;

- Announce top-line results from the Phase 3 trial (NCT03663205) comparing tislelizumab plus chemotherapy to chemotherapy alone in first-line patients with non-squamous NSCLC in China in 2020;

- 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; and

- Complete enrollment in the global portion of the Phase 3 trial (NCT03358875) comparing tislelizumab with docetaxel in second-or third-line patients with NSCLC and in the global Phase 3 trial (NCT03430843) comparing tislelizumab with chemotherapy in second-line patients with advanced ESCC in early 2020 and announce top-line results in 2020 or early 2021.

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

- Disclosed plans to convert from Phase 3 to Phase 2 the clinical trial of pamiparib vs. placebo as maintenance therapy in patients with inoperable locally advanced or metastatic gastric cancer who have responded to platinum-based first line chemotherapy (NCT 03427814; also known as the BGB-290-303 trial). The Company plans to evaluate data from the Phase 2 trial to assess the potential of pamiparib in this indication and the potential next steps of development as a monotherapy or in combination with other therapies.

Expected Milestones for Pamiparib

- Have regulatory discussions based on preliminary results from the Phase 2 trial (NCT03333915) in Chinese patients with third or later line previously treated ovarian cancer (OC) harboring germline BRCA 1/2 mutations and potentially submit a new drug application (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 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.

***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*

- Presented clinical data in an oral session at the European Society for Medical Oncology Immuno-Oncology (ESMO-IO) Congress in December 2019 from the Phase 1b trial (NCT03666143) of sitravatinib combined with tislelizumab in patients with platinum-resistant OC.

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.*

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; and

- Initiate a Phase 1b/2 trial investigating ZW25 in combination with chemotherapy with and without tislelizumab in patients with advanced HER2-positive breast cancer or gastric/gastroesophageal junction adenocarcinoma in early 2020.

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

Expected Milestones for Lifirafenib

- Publish Phase 1 data in a peer-reviewed journal in 2020.

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-A445, *an investigational non-ligand competing anti OX40 agonistic monoclonal antibody*

- Initiated a Phase 1 trial (NCT04215978) of BGB-A445 as monotherapy and in combination with tislelizumab in patients with advanced solid tumors.

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

- Initiated a Phase 1 clinical trial (NCT04249843) in patients with advanced or refractory tumors harboring specific v-RAF murine sarcoma viral oncogene homolog B (B-RAF) genetic mutations.

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

- Initiated study start-up for a Phase 1 trial in Australia and the United States in patients with mature B-cell malignancies.

Expected Milestones for BGB-11417

- Begin patient enrollment for the Phase 1 trial in mature B-cell malignancies in the first quarter or early in the second quarter of 2020.

Manufacturing Facilities

- Received a drug manufacturing license for our Guangzhou biologics manufacturing facility in December 2019;
- Initiated tislelizumab manufacturing process validation; and
- Began Phase 2 expansion for additional manufacturing capacity at our Guangzhou manufacturing facility, expected to be completed by the end of 2020.

Corporate Developments

- Closed the global strategic collaboration with Amgen to commercialize XGEVA® (denosumab), KYPROLIS® (carfilzomib), and BLINCYTO® (blinatumomab) in China and jointly develop 20 Amgen oncology pipeline assets. Amgen purchased approximately $2.8 billion of BeiGene's American Depositary Shares (ADS), representing an approximately 20.5% ownership interest;
- Announced an exclusive development and commercialization agreement with EUSA Pharma (UK) Limited for the orphan biologic products SYLVANT® (siltuximab) in Greater China and QARZIBA®▼ (dinutuximab beta) in mainland China; and
- Announced an exclusive option and license agreement with Leap Therapeutics, Inc. for the clinical development and commercialization of DKN-01, Leap's anti-Dickkopf-1 (DKK1) antibody, in Asia (excluding Japan), Australia, and New Zealand.

Expected COVID-19 Impact

- The Company expects that the worldwide health crisis of COVID-19 will have a negative impact on its operations in China, including commercial sales, regulatory interactions and inspections, and clinical trial recruitment and participation, particularly in the first quarter and possibly longer depending on the scope and duration of the disruption. The Company is working to minimize delays and disruptions and continues to execute on its commercialization, regulatory and clinical development goals in China.

Fourth Quarter and Full Year 2019 Financial Results

Cash, Cash Equivalents, Restricted Cash and Short-Term Investments were $985.50 million as of December 31, 2019, compared to $1.28 billion as of September 30, 2019 and $1.81 billion as of December 31, 2018. Cash and

cash equivalents as of December 31, 2019 does not include $2.8 billion of cash received from the sale of ADSs to Amgen in connection with the closing of the Amgen collaboration on January 2, 2020.

- Total cash and short-term investments decreased $291.09 million in the fourth quarter of 2019. Cash used in operating activities totaled $267.18 million. Capital expenditures were $15.46 million, and cash used for upfront license payments totaled $20.00 million.

- Total cash and short-term investments decreased $823.72 million for the year ended December 31, 2019. Cash used in operating activities totaled $750.27 million. Capital expenditures were $89.61 million, and cash used for upfront license payments totaled $69.00 million.

Revenue for the fourth quarter and year ended December 31, 2019 was $56.89 million and $428.21 million, respectively, compared to $58.67 million and $198.22 million in the same periods in 2018. The slight decrease in total revenue in the quarter compared to the prior year is attributable to the lack of collaboration revenue after the termination of the Celgene collaboration agreement for tislelizumab, offset in part by increased product sales of ABRAXANE, REVLIMID, and VIDAZA in China and the initial sales of BRUKINSA in the United States. The increase in the year-over-year period is primarily due to the $150 million payment in connection with the termination of the tislelizumab collaboration agreement with Celgene Corp., a Bristol-Myers Squibb company (BMS), as well as increased product sales.

- Product revenues totaled $56.89 million and $222.60 million for the fourth quarter and year ended December 31, 2019, respectively, compared to $37.76 million and $130.89 million for the same periods in 2018.

- Collaboration revenue totaled nil and $205.62 million for the fourth quarter and year ended December 31, 2019, respectively, compared to $20.91 million and $67.34 million for the same periods in 2018. Included in the full year 2019 revenue was the $150 million payment in connection with the termination of the tislelizumab collaboration agreement with Celgene.

Expenses for the fourth quarter and year ended December 31, 2019 were $444.93 million and $1.39 billion, respectively, compared to $339.48 million and $903.99 million in the same periods in 2018.

- **Cost of Sales** for the fourth quarter and year ended December 31, 2019 were $17.98 million and $71.19 million, respectively, compared to $9.19 million and $28.71 million in the same periods in 2018. Cost of sales related primarily 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, 2019 were $283.26 million and $927.34 million, respectively, compared to $257.46 million and $679.01 million in the same periods in 2018. The increase in R&D expenses was primarily attributable to increased spending related to ongoing enrollment and expansion of pivotal clinical trials for zanubrutinib and tislelizumab, preparation for additional regulatory submissions 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. Employee share-based compensation expense also contributed to the overall increase in R&D expenses, and was $21.69 million and $76.29 million for the fourth quarter and year ended December 31, 2019, respectively, compared to $16.09 million and $54.38 million for the same periods in 2018, due to increased headcount and a higher share price.

- **SG&A Expenses** for the fourth quarter and year ended December 31, 2019 were $143.35 million and $388.25 million, respectively, compared to $72.49 million and $195.39 million in the same periods in 2018. The increase in SG&A expenses was primarily attributable to increased headcount, including the expansion of our commercial teams to support the distribution of our commercial products in China and in the United States, increased commercial activities 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 $16.65 million and $57.86 million for the fourth quarter and year ended December 31, 2019, respectively, compared to $9.87 million and $32.74 million for the same periods in 2018, due to increased headcount and a higher share price.

- **Net Loss** for the fourth quarter and year ended December 31, 2019 was $388.06 million and $948.63 million, or $0.49 and $1.22 per share, or $6.39 and $15.80 per ADS, respectively, compared to $268.26 million and $673.77 million, or $0.35 and $0.93 per share, or $4.52 and $12.15 per ADS, respectively, in the same periods in 2018.

Financial Summary

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

(Amounts in thousands of U.S. Dollars)

(Audited)

	As of	
	December 31, 2019	December 31, 2018
Assets:		
Cash, cash equivalents, restricted cash and short-term investments [1]	$ 985,503	$ 1,809,222
Accounts receivable	70,878	41,056
Working capital	862,384	1,697,390
Property and equipment, net	242,402	157,061
Total assets	$ 1,612,289	$ 2,249,684
Liabilities and equity:		
Accounts payable	$ 122,488	$ 113,283
Accrued expenses and other payables	163,556	100,414
Bank loan	83,311	49,512
Shareholder loan	157,384	148,888
Total liabilities	633,934	496,037
Noncontrolling interest	16,150	14,445
Total equity	$ 978,355	$ 1,753,647

[1] Cash, cash equivalents, restricted cash and short-term investments as of December 31, 2019 does not include $2.8 billion of cash received from the sale of ADSs to Amgen in connection with the closing of the Amgen collaboration on January 2, 2020.

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,	
	2019	2018	2019	2018
	(unaudited)		(audited)	
Revenue:				
Product revenue, net	$ 56,892	$ 37,762	$ 222,596	$ 130,885
Collaboration revenue	—	20,908	205,616	67,335
Total revenues	56,892	58,670	428,212	198,220
Expenses:				
Cost of sales - products	(17,984)	(9,193)	(71,190)	(28,705)
Research and development [1]	(283,259)	(257,464)	(927,338)	(679,005)
Selling, general and administrative	(143,354)	(72,490)	(388,249)	(195,385)
Amortization of intangible assets	(332)	(331)	(1,326)	(894)
Total expenses	(444,929)	(339,478)	(1,388,103)	(903,989)
Loss from operations	(388,037)	(280,808)	(959,891)	(705,769)
Interest (expense) income, net	(438)	5,950	9,131	13,947
Other income (expense), net	8,141	(396)	7,174	1,993
Loss before income taxes	(380,334)	(275,254)	(943,586)	(689,829)
Income tax (expense) benefit	(7,561)	8,544	(6,992)	15,796
Net loss	(387,895)	(266,710)	(950,578)	(674,033)
Less: Net income (loss) attributable to noncontrolling interest	166	1,545	(1,950)	(264)
Net loss attributable to BeiGene, Ltd.	$ (388,061)	$ (268,255)	$ (948,628)	$ (673,769)
Net loss per share attributable to BeiGene,	$ (0.49)	$ (0.35)	$ (1.22)	$ (0.93)

Ltd., basic and diluted				
Weighted-average shares outstanding, basic and diluted	788,899,247	771,982,215	780,701,283	720,753,819
Net loss per ADS attributable to BeiGene, Ltd., basic and diluted	$ (6.39)	$ (4.52)	$ (15.80)	$ (12.15)
Weighted-average ADSs outstanding, basic and diluted	60,684,557	59,383,247	60,053,945	55,442,601

[1] Research and development expense for the fourth quarter and year ended December 31, 2019 includes expenses related to in-process research and development collaborations totaling $20 million and $50 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 3,500 employees in the United States, China, 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. In the United States, BeiGene markets and distributes BRUKINSA™ (zanubrutinib) and in China, the Company has received approval to market its anti-PD-1 antibody tislelizumab and markets ABRAXANE® (nanoparticle albumin-bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) under a license from Celgene Logistics Sàrl, a Bristol-Myers Squibb company,[i] and plans to market XGEVA® (denosumab) under a collaboration with Amgen.[ii] For more information please visit www.beigene.com.

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; the impact of the coronavirus 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 coronavirus 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 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	Media Contact
Craig West	Vivian Ni
+1 857-302-5189	+ 1 857-302-7596
ir@beigene.com	media@beigene.com

[i] ABRAXANE® is a registered trademark of Abraxis Bioscience LLC, a Bristol-Myers Squibb company; REVLIMID® and VIDAZA® are registered trademarks of Celgene Corporation, a Bristol-Myers Squibb company.

[ii] XGEVA® is a registered trademark of Amgen.