# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
# Washington, D.C. 20549

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# FORM 8-K

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## CURRENT REPORT

### Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): December 15, 2018

## BEIGENE, LTD.

(Exact Name of Registrant as Specified in Charter)

| **Cayman Islands** | **001-37686** | **98-1209416** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (I.R.S. Employer Identification Number) |

**c/o Mourant Ozannes Corporate Services (Cayman) Limited**
**94 Solaris Avenue, Camana Bay**
**Grand Cayman KY1-1108**
**Cayman Islands**
(Address of Principal Executive Offices) (Zip Code)

**+1 (345) 949 4123**
(Registrant's telephone number, including area code)

**Not Applicable**
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

**Item 1.02. Termination of a Material Definitive Agreement.**

On December 17, 2018, BeiGene, Ltd. (the "Company") and Merck KGaA ("Merck KGaA") entered into a letter agreement for the Company to buy back the commercialization option it had granted to Merck KGaA under the parties' License Agreement (the "License Agreement") dated October 28, 2013, as amended, for the Company's investigational PARP inhibitor pamiparib (BGB-290) in the People's Republic of China, for an undisclosed payment by the Company to Merck KGaA. As a result of the letter agreement, as of December 31, 2018, the License Agreement will be terminated and Merck KGaA will be relieved of any future milestone obligations to the Company under the License Agreement.

**Item 8.01. Other Events.**

On December 15, 2018, the Company issued a press release announcing that updated clinical data from an ongoing Phase 1A/1B trial of tislelizumab, an investigational anti-PD-1 antibody, were presented in an oral session and a poster at the European Society for Medical Oncology Immuno-Oncology (ESMO-IO) Congress, held December 13-16 in Geneva, Switzerland. The full text of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On December 17, 2018, the Company issued a press release announcing that the first patients have been enrolled in two global Phase 3 clinical trials of tislelizumab. These trials are evaluating tislelizumab combined with chemotherapy as potential first-line treatments in patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, and in patients with unresectable, locally advanced recurrent or metastatic esophageal squamous cell carcinoma. The full text of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release titled "BeiGene Announces Updated Phase 1A/1B Data on Tislelizumab Presented at the European Society for Medical Oncology Immuno-Oncology Congress" issued on December 15, 2018 |
| 99.2 | Press Release titled "BeiGene Initiates Two Global Phase 3 Front-Line Clinical Trials of Tislelizumab, for Patients with Gastric Cancer and for Patients with Esophageal Cancer" issued on December 17, 2018 |

**Exhibit Index**

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**BEIGENE, LTD.**

Date: December 20, 2018

By: /s/ Scott A. Samuels
Scott A. Samuels
Senior Vice President, General Counsel

# BeiGene Announces Updated Phase 1A/1B Data on Tislelizumab Presented at the European Society for Medical Oncology Immuno-Oncology Congress

CAMBRIDGE, Mass. and BEIJING, China, Dec. 15, 2018 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, announced that updated clinical data from an ongoing Phase 1A/1B trial of tislelizumab, an investigational anti-PD-1 antibody, were presented in an oral session and a poster at the European Society for Medical Oncology Immuno-Oncology (ESMO-IO) Congress, being held December 13-16 in Geneva, Switzerland.

“We continue to be pleased with the results of tislelizumab in solid tumors,” commented Amy Peterson, M.D., Chief Medical Officer, Immuno-Oncology, at BeiGene. “We believe that these updated results provide support for the continued development of tislelizumab in patients with bladder, esophageal, stomach, liver and non-small cell lung cancers, and we have registration-enabling studies ongoing or planned to start soon in each of these indications.”

**Summary of ESMO-IO Presentations from the Ongoing Phase 1A/1B Trial**
The multi-center, open-label Phase 1A/1B trial (NCT02407990) of tislelizumab as monotherapy in advanced solid tumors is being conducted in Australia, New Zealand, the United States, Taiwan and South Korea and consists of dose-escalation and dose-expansion phases in disease-specific cohorts.

***Updated Results in Patients with Urothelial Carcinoma (UC)***
Data presented at ESMO-IO included updated results from an analysis of tislelizumab in 17 patients with UC. At the time of the data cutoff on August 31, 2018, median treatment duration was 4.1 months (0.7-30.4 months), with two patients still on treatment.

Treatment-related adverse events (TRAEs) as assessed by the investigator occurred in 15 patients (88.2%). Of those, fatigue (n=5), infusion-related reactions (n=3), rash (n=3), nausea (n=2), pain in extremity (n=2), peripheral adema (n=2), and proteinuria (n=2) occurred in two or more patients. Three treatment-related Grade 3 or 4 AEs occurred in two patients, fatigue (n=1), and hyperglycemia and latent autoimmune diabetes (n=1). One patient discontinued treatment due to recurrent infusion-related reactions considered related to tislelizumab.

At the time of the data cutoff, all 17 patients were evaluable for response, defined as having a baseline tumor assessment with at least one post-baseline tumor response assessment, or progression or death. The confirmed response rate was 29.4 percent, with one complete response (CR) and four partial responses (PR). Three additional patients achieved stable disease (SD) as their best response. There was one CR, one PR and one SD among the eight patients with PD-L1 high tumors and two PRs and two SDs among the eight patients with PD-L1 low or negative tumors (one tumor was not-evaluable for PD-L1 expression). The median duration of response was 18.7 months (6.2-18.7 months).

***Updated Results in Patients with Esophogeal, Gastric, Hepatocellular and Non-Small Cell Lung Cancers***
In an oral presentation at ESMO-IO, data on patients with esophageal (EC, n=54), gastric (GC, n=54), hepatocellular (HC, n=50) and non-small cell lung cancers (NSCLC, n=49) were reported.

TRAEs occurring in at least five percent of patients across all cohorts included fatigue (8.7%), pruritis (7.7%), hypothyroidism (7.2%), decreased appetite (6.8%), rash (6.8%) and nausea (6.3%). Ten patients experienced one or more serious adverse events considered related to tislelizumab, including pneumonitis (n=3) and one case each of acute hepatitis, dermatitis, diarrhea, increased ALT, increased AST, infusion-related reaction, pyrexia and vomiting. Grade 3 or 4 TRAEs occurring in more than one patient included increased AST (n=4), increased ALT (n=3) and pneumonitis (n=2). There were two fatal TRAEs reported, including acute hepatitis in a patient with HCC confounded by rapidly progressive disease, and pneumonitis in a patient with NSCLC with compromised pulmonary capacity at baseline.

Confirmed response rates and disease control rates in patients with EC were 11.1 percent and 37.0 percent, respectively; 13.0 percent and 29.6 percent in patients with GC, respectively; 12.2 percent and 51.0 percent in patients with HCC, respectively, and 13.0 percent and 63.0 percent in patients with NSCLC, respectively. For patients with EC and NSCLC, the median duration of response (mDOR) had not been reached. The mDOR in patients with GC was 8.5 months and for patients with HCC it was 15.7 months.

**About Tislelizumab**
Tislelizumab (BGB-A317) is an investigational humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages. In pre-clinical studies, binding to FcγR on macrophages has been shown to compromise the anti-tumor activity of PD-1 antibodies through activation of antibody-dependent macrophage-mediated killing of T effector cells.

Discovered by BeiGene scientists, tislelizumab is being developed as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers. The new drug application (NDA) for tislelizumab in China for patients with relapsed/refractory (R/R) classical Hodgkin's lymphoma (cHL) has been accepted by the China National Medical Products Administration (NMPA, formerly known as CFDA) and granted priority review status. BeiGene and Celgene Corporation have a global strategic collaboration for the development of tislelizumab in solid tumors in the United States, Europe, Japan and the rest of world outside Asia.

**About BeiGene**
BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly-targeted and immuno-oncology cancer therapeutics. With a team of over 1,700 employees in China, the United States, Australia and Switzerland, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. BeiGene markets ABRAXANE® (nanoparticle albumin–bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) in China under a license from Celgene Corporation.[i]

**Forward-Looking Statements**
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the encouraging clinical data from clinical trials of tislelizumab and BeiGene’s advancement of, and anticipated clinical development, regulatory milestones and commercialization of tislelizumab. 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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[i] ABRAXANE®, REVLIMID®, and VIDAZA® are registered trademarks of Celgene Corporation.

# BeiGene Initiates Two Global Phase 3 Front-Line Clinical Trials of Tislelizumab, in Patients with Gastric Cancer and in Patients with Esophageal Cancer

CAMBRIDGE, Mass., and BEIJING, China, Dec. 17, 2018 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced that the first patients have been enrolled in two global Phase 3 clinical trials of its investigational anti-PD-1 antibody, tislelizumab. These trials are evaluating tislelizumab combined with chemotherapy as potential first-line treatments in patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, and in patients with unresectable, locally advanced recurrent or metastatic esophageal squamous cell carcinoma (ESCC).

“Available data have shown promise for anti-PD-1 antibodies in patients with advanced gastric or gastroesophageal adenocarcinoma and in patients with advanced esophageal carcinoma. We are looking forward to investigating tislelizumab globally in these Phase 3 trials,” said Amy Peterson, M.D., Chief Medical Officer, Immuno-Oncology, at BeiGene. “Gastric and esophageal cancers are among the most common malignancies in Asia and collectively are responsible for over 800,000 deaths annually in China[1] alone. We are hopeful that these global studies of tislelizumab may ultimately lead to improved treatment options for patients diagnosed with these malignancies.”

**Global Phase 3 Trial in Advanced Gastric or Gastroesophageal Adenocarcinoma**

The global, randomized, double-blind, placebo-controlled Phase 3 trial is designed to enroll 720 patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma. Patients will either receive 200 mg of tislelizumab or placebo combined with platinum- and fluoropyrimidine-based chemotherapy, the standard chemotherapy treatment, intravenously once every three weeks.

The co-primary endpoints will be progression-free survival (PFS) and overall survival (OS). Secondary endpoints include overall response rate (ORR), duration of response (DOR) and quality of life (QoL), as well as safety and tolerability.

**Global Phase 3 Trial in Advanced ESCC**

The global, randomized, double-blind, placebo-controlled Phase 3 trial is designed to enroll 480 patients with unresectable, locally advanced recurrent, or metastatic ESCC. Patients will either receive 200 mg of tislelizumab or placebo combined with platinum- and fluoropyrimidine-based chemotherapy, intravenously once every three weeks.

The co-primary endpoints will be PFS and OS. Secondary endpoints include ORR, DOR, and QoL, as well as safety and tolerability.

For more information about these trials, patients and physicians should email BeiGene at clinicaltrials@beigene.com.

**About Tislelizumab**
Tislelizumab (BGB-A317) is an investigational humanized IgG4 anti–PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages. In pre-clinical studies, binding to FcγR on macrophages has been shown to compromise the anti-tumor activity of PD-1 antibodies through activation of antibody-dependent macrophage-mediated killing of T effector cells.

Discovered by BeiGene scientists, tislelizumab is being developed as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers. The new drug application (NDA) for tislelizumab in China for patients with R/R cHL has been accepted by the China National Medical Products Administration (NMPA, formerly known as CFDA) and granted priority review status. BeiGene and Celgene Corporation have a global strategic collaboration for the development of tislelizumab in solid tumors in the United States, Europe, Japan, and the rest of world outside Asia.

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[1] Chen, W. e. (2016). Cancer statistics in China, 2015. CA Cancer J Clin, 66(2), 115-32.

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