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**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): January 21, 2020

**BEIGENE, LTD.**  
(Exact Name of Registrant as Specified in Charter)

**Cayman Islands**  
(State or Other Jurisdiction of Incorporation)

**001-37686**  
(Commission File Number)  
c/o Mourant Governance 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)

**98-1209416**  
(I.R.S. Employer Identification Number)

**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))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
<b>American Depositary Shares, each representing 13 Ordinary Shares, par value \$0.0001 per share</b>	<b>BGNE</b>	<b>The NASDAQ Global Select Market</b>
<b>Ordinary Shares, par value \$0.0001 per share*</b>	<b>06160</b>	<b>The Stock Exchange of Hong Kong Limited</b>

\*Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

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.

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**Item 8.01. Other Events.**

On January 21, 2020, BeiGene, Ltd. (the “Company”) announced that the pivotal Phase 3 trial evaluating its anti-PD-1 antibody tislelizumab in combination with two chemotherapy regimens 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 planned interim analysis, as assessed by independent review committee (IRC). A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

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

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by the Company on January 21, 2020
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release issued by the Company on January 21, 2020</a>
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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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: January 21, 2020

By: /s/ Scott A. Samuels

Name: Scott A. Samuels

Title: Senior Vice President, General Counsel



## **BeiGene Announces that the Phase 3 Clinical Trial of its Anti-PD-1 Antibody Tislelizumab in Patients with First-Line Squamous Non-Small Cell Lung Cancer Met the Primary Endpoint of Progression-Free Survival at Interim Analysis**

BEIJING, China, and CAMBRIDGE, MA, January 21, 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 announced that the pivotal Phase 3 trial evaluating its anti-PD-1 antibody tislelizumab in combination with two chemotherapy regimens 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 planned interim analysis, as assessed by independent review committee (IRC). In this study, patients with previously untreated advanced squamous NSCLC were randomized to receive either tislelizumab in combination with paclitaxel and carboplatin, tislelizumab in combination with nanoparticle albumin-bound (*nab*) paclitaxel (ABRAXANE®) and carboplatin, or paclitaxel and carboplatin alone. Based on the pre-planned interim analysis, both tislelizumab treatment arms crossed the pre-specified efficacy boundary compared to chemotherapy alone. 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.

“Tislelizumab was recently approved in China for patients with relapsed or refractory classical Hodgkin’s lymphoma, and we have a broad development program with more than 5,000 patients enrolled in over 25 tislelizumab studies, including 15 potentially registration-enabling trials,” commented Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. “We are extremely excited about the compelling results that tislelizumab demonstrated in this Phase 3 trial and for its potential use as a first-line treatment for patients in China with advanced squamous NSCLC. We look forward to continuing the development program for tislelizumab in lung cancer, which includes three other Phase 3 trials, and reporting additional data.”

The company plans to discuss its plans for filing a supplemental new drug application (sNDA) for tislelizumab as a first-line treatment for squamous NSCLC with the Center for Drug Evaluation (CDE) at the National Medical Products Administration (NMPA) in China and to present these data at an upcoming medical meeting.

This trial (NCT 03594747, known as BGB-A317-307) is a Phase 3, randomized, open-label, multi-center trial investigating tislelizumab combined with either paclitaxel and carboplatin or *nab*-paclitaxel (ABRAXANE, which is commercialized by BeiGene in China) and carboplatin compared with paclitaxel and carboplatin alone in patients with

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untreated stage IIIB or IV squamous NSCLC from mainland China, regardless of PD-L1 expression. The primary endpoint is PFS per IRC. Key secondary endpoints include overall survival and safety. The study began enrolling patients in July 2018, and 360 patients were randomized 1:1:1 to receive tislelizumab (200mg every three weeks) in combination with each of the chemotherapy regimens or chemotherapy only, until disease progression, unacceptable toxicity, physician decision or consent withdrawal. Patients on the chemotherapy-only control arm who experienced disease progression, verified by central independent review, were eligible to cross over to receive tislelizumab monotherapy.

“Squamous NSCLC remains a significant unmet need, representing approximately 30 percent of patients with NSCLC in China. This Phase 3 study was designed to assess the impact of tislelizumab given in combination with chemotherapy as a potential treatment to improve outcomes in patients with advanced squamous NSCLC, for whom prognoses are typically quite poor. These results give us hope that we could have a new treatment option for these patients,” commented Jie Wang, M.D., Professor at the Cancer Hospital Chinese Academy of Medical Sciences, in Beijing, China and lead investigator for the trial.

### **About Non-Small Cell Lung Cancer**

In contrast to most Western countries where lung cancer death rates are decreasing, lung cancer incidence rate is still increasing in China.<sup>12</sup> There were approximately 770,000 new cases of lung cancer in China in 2018 and it is the leading cause of cancer-related death in both men and women, with approximately 690,500 deaths in China in 2018.<sup>3</sup> Non-small cell lung cancer (NSCLC) comprises the most common form of lung cancer in China.<sup>4</sup>

### **About Tislelizumab**

Tislelizumab (BGB-A317) is a 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. Tislelizumab is the first drug from BeiGene’s immuno-oncology biologics program and 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.

Tislelizumab is approved by the China National Medical Products Administration (NMPA) as a treatment for patients with classical Hodgkin’s lymphoma who received at

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least two prior therapies. A supplemental new drug application (sNDA) for tislelizumab in patients with previously treated locally advanced or metastatic urothelial carcinoma has been granted priority review by the Center for Drug Evaluation at the NMPA and is currently under review.

Tislelizumab is being studied in a broad clinical program as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers. Currently, 15 potentially registration-enabling clinical trials are being conducted in China and globally, including 11 Phase 3 trials and four pivotal Phase 2 trials.

Tislelizumab is not approved for use outside of China.

### **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 3,400 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 Sarl, a Bristol-Myers Squibb company,<sup>5</sup> and plans to market XGEVA® (denosumab) under a license from Amgen.<sup>6</sup> For more information please visit [www.beigene.com](http://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 data from the BGB-A317-307 Phase 3 trial of tislelizumab in patients with previously untreated advanced squamous NSCLC and other clinical trials of tislelizumab, the potential implications of clinical data for patients, BeiGene's plans to discuss data from the BGB-A317-307 trial with the NMPA and present the data at an upcoming medical meeting, 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

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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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<sup>1</sup> Jemal A, Bray F, Center MM, et al. Global cancer statistics. *CA Cancer J Clin* 2011;61:69-90.

<sup>2</sup> She J, Yang P, Hong Q, et al. Lung cancer in China: challenges and interventions. *Chest* 2013;143:1117-26.

<sup>3</sup> Feng et al. *Cancer Communications* (2019) 39:22 <https://doi.org/10.1186/s40880-019-0368-6>

<sup>4</sup> Siegel R, DeSantis C, Virgo K, et al. Cancer treatment and survivorship statistics, 2012. *CA Cancer J Clin* 2012;62:220-41.

<sup>5</sup> 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

<sup>6</sup> XGEVA® is a registered trademark of Amgen