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

Form 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event Reported): June 14, 2019

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 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)

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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 13 Ordinary Shares, par value $0.0001 per share	**BGNE**	**The NASDAQ Global Select Market**
Ordinary Shares, par value $0.0001 per share*	**6160**	**The Stock Exchange of Hong Kong Limited**

*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. [ ]

Item 1.02. Termination of a Material Definitive Agreement.

On June 14, 2019, BeiGene, Ltd. and its wholly-owned subsidiary, BeiGene Switzerland GmbH (collectively, "BeiGene"), and Celgene Corporation and its wholly-owned subsidiary Celgene Switzerland LLC (collectively, "Celgene") entered into an agreement to mutually terminate their Amended and Restated Exclusive License and Collaboration Agreement, dated August 31, 2017, pursuant to which BeiGene had granted an exclusive license to Celgene to develop and commercialize tislelizumab for solid tumors in the United States, Europe, Japan and the rest of the world other than Asia (the "Collaboration Agreement"). In connection with the termination, Celgene will pay $150 million to BeiGene and BeiGene will regain full, global development and commercialization rights to tislelizumab.

The License and Supply Agreement entered into as of July 5, 2017 by and among BeiGene and Celgene Logistics Sàrl remains unchanged, and BeiGene retains the right to exclusively distribute and promote ABRAXANE®, REVLIMID®, and VIDAZA® in China, excluding Hong Kong, Macau and Taiwan, pursuant to the terms of the agreement.

Item 7.01. Regulation FD Disclosure.

BeiGene will host a conference call and webcast of mid-2019 clinical data updates on Thursday, June 20, 2019 at 8:00 a.m. EDT. The information in Item 7.01 of this Current Report on Form 8-K is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On June 17, 2019, BeiGene issued a press release announcing the above-described transaction. 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.

On June 14, 2019, BeiGene issued a press release announcing the first presentation of clinical results from the ASPEN trial, a global randomized Phase 3 open-label trial of its investigational BTK inhibitor zanubrutinib in patients with Waldenström's Macroglobulinemia (WM). The poster presentation included clinical results from a nonrandomized exploratory cohort of patients with the $MYD88^{WT}$ genotype of WM. The Company also announced updated results from the ongoing Phase 1/2 trial of patients with WM; and a pooled safety data analysis of zanubrutinib from six ongoing monotherapy studies in patients with B-cell malignancies. These data were presented in three posters at the 24th European Hematology Association (EHA) Congress, taking place June 13-16, 2019 in Amsterdam. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and incorporated by reference herein.

On June 14, 2019, BeiGene issued a press release announcing updated results from a pivotal Phase 2 study of tislelizumab, an investigational anti-PD-1 antibody, in Chinese patients with relapsed/refractory (R/R) classical Hodgkin lymphoma (cHL) in a poster at the 24th EHA Congress. A copy of the press release is filed as Exhibit 99.3 to this Current Report on Form 8-K and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "BeiGene Regains Full Global Rights to Its Investigational Anti-PD-1 Antibody Tislelizumab," issued on June 17, 2019
99.2	Press Release titled "BeiGene Announces Clinical Results from Three Posters on Zanubrutinib Presented at the 24th Congress of European Hematology Association (EHA)," issued on June 14, 2019
99.3	Press Release titled "BeiGene Announces Updated Results from a Pivotal Phase 2 Study of Tislelizumab in Chinese Patients with Relapsed or Refractory Classical Hodgkin Lymphoma at the 24th Congress of the European Hematology Association (EHA)," issued on June 14, 2019

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: June 17, 2019

By: /s/ Scott A. Samuels

Name: Scott A. Samuels

Title: Senior Vice President, General Counsel

BeiGene Announces Acceptance of Supplemental Import Drug Application in China for ABRAXANE® in Metastatic Pancreatic Cancer

CAMBRIDGE, Mass. and BEIJING, China; May 30, 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 announced that the China National Medical Products Administration (NMPA, formerly known as CFDA) has accepted the supplemental import drug application for ABRAXANE® (paclitaxel protein-bound particles for injectable suspension) (albumin-bound), in combination with gemcitabine, as a first-line treatment of patients with metastatic adenocarcinoma of the pancreas (mPC). ABRAXANE was first approved in China in 2008 for the treatment of patients with metastatic breast cancer. It is currently marketed in China by BeiGene under an exclusive license from Celgene Corporation.

“We’re delighted about the NMPA’s acceptance of the supplemental import drug submission of ABRAXANE as a treatment for Chinese patients with metastatic adenocarcinoma of the pancreas,” said Dr. Xiaobin Wu, General Manager of China and President of BeiGene. “ABRAXANE has been an important global treatment option for patients with metastatic adenocarcinoma of the pancreas outside of China, and we strive to provide access to ABRAXANE in China to those patients for whom there is great need for additional treatments to combat this deadly disease.”

About Pancreatic Cancer
Pancreatic cancer is one of the deadliest cancers, with a nine percent five-year survival rate. In 2018, there were an estimated 458,918 new cases globally, making it the 12th most common cancer in the world. Pancreatic cancer is difficult to detect in early stages, as the disease does not cause obvious symptoms. In addition, the pancreas is located deep in the abdomen, hindering the diagnosis of pancreatic cancer.

About ABRAXANE in Pancreatic Cancer

In September 2013, the U.S. Food and Drug Administration (FDA) approved ABRAXANE in combination with gemcitabine as first-line treatment of patients with metastatic adenocarcinoma of the pancreas.

Clinical trials continue building on the foundation of ABRAXANE in combination with gemcitabine for a new wave of potential treatments, such as an ongoing Phase 2 cooperative group trial with SWOG S1505 (ClinicalTrials.gov, NCT02562716) investigating the safety and effectiveness of ABRAXANE in combination with gemcitabine as neoadjuvant treatment for localized pancreatic head adenocarcinoma.

Indications

ABRAXANE® is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

ABRAXANE is indicated for the first-line treatment of locally advanced or metastatic non– small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.

ABRAXANE is indicated for the first-line treatment of patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.

Important Safety Information

WARNING - NEUTROPENIA

- **Do not administer ABRAXANE therapy to patients who have baseline neutrophil counts of less than 1500 cells/mm3. In order to monitor the occurrence of bone marrow suppression, primarily neutropenia, which may be severe and result in infection, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving ABRAXANE**

- **Note: An albumin form of paclitaxel may substantially affect a drug's functional properties relative to those of drug in solution. DO NOT SUBSTITUTE FOR OR WITH OTHER PACLITAXEL FORMULATIONS**

CONTRAINDICATIONS
Neutrophil Counts
- ABRAXANE should not be used in patients who have baseline neutrophil counts of <1500 cells/mm3

Hypersensitivity
- Patients who experience a severe hypersensitivity reaction to ABRAXANE should not be rechallenged with the drug

WARNINGS AND PRECAUTIONS
Hematologic Effects
- Bone marrow suppression (primarily neutropenia) is dose-dependent and a dose-limiting toxicity of ABRAXANE. In clinical studies, Grade 3-4 neutropenia occurred in 34% of patients with metastatic breast cancer (MBC), 47% of patients with non–small cell lung cancer (NSCLC), and 38% of patients with pancreatic cancer
- Monitor for myelotoxicity by performing complete blood cell counts frequently, including prior to dosing on Day 1 (for MBC) and Days 1, 8, and 15 (for NSCLC and for pancreatic cancer)
- Do not administer ABRAXANE to patients with baseline absolute neutrophil counts (ANC) of less than 1500 cells/mm3
- In the case of severe neutropenia (<500 cells/mm3 for 7 days or more) during a course of ABRAXANE therapy, reduce the dose of ABRAXANE in subsequent courses in patients with either MBC or NSCLC
- In patients with MBC, resume treatment with every-3-week cycles of ABRAXANE after ANC recovers to a level >1500 cells/mm3 and platelets recover to a level >100,000 cells/mm3
- In patients with NSCLC, resume treatment if recommended at permanently reduced doses for both weekly ABRAXANE and every-3-week carboplatin after ANC recovers to at least 1500 cells/mm3 and platelet count of at least 100,000 cells/mm3 on Day 1 or to an ANC of at least 500 cells/mm3 and platelet count of at least 50,000 cells/mm3 on Days 8 or 15 of the cycle

- In patients with adenocarcinoma of the pancreas, withhold ABRAXANE and gemcitabine if the ANC is less than 500 cells/mm3 or platelets are less than 50,000 cells/mm3 and delay initiation of the next cycle if the ANC is less than 1500 cells/mm3 or platelet count is less than 100,000 cells/mm3 on Day 1 of the cycle. Resume treatment with appropriate dose reduction if recommended

Nervous System
- Sensory neuropathy is dose- and schedule-dependent
- The occurrence of Grade 1 or 2 sensory neuropathy does not generally require dose modification
- If ≥ Grade 3 sensory neuropathy develops, withhold ABRAXANE treatment until resolution to Grade 1 or 2 for MBC or until resolution to ≤ Grade 1 for NSCLC and pancreatic cancer followed by a dose reduction for all subsequent courses of ABRAXANE

Sepsis
- Sepsis occurred in 5% of patients with or without neutropenia who received ABRAXANE in combination with gemcitabine
- Biliary obstruction or presence of biliary stent were risk factors for severe or fatal sepsis
- If a patient becomes febrile (regardless of ANC), initiate treatment with broad-spectrum antibiotics
- For febrile neutropenia, interrupt ABRAXANE and gemcitabine until fever resolves and ANC ≥1500 cells/mm3, then resume treatment at reduced dose levels

Pneumonitis
- Pneumonitis, including some cases that were fatal, occurred in 4% of patients receiving ABRAXANE in combination with gemcitabine
- Monitor patients for signs and symptoms and interrupt ABRAXANE and gemcitabine during evaluation of suspected pneumonitis
- Permanently discontinue treatment with ABRAXANE and gemcitabine upon making a diagnosis of pneumonitis

Hypersensitivity
- Severe and sometimes fatal hypersensitivity reactions, including anaphylactic reactions, have been reported
- Patients who experience a severe hypersensitivity reaction to ABRAXANE should not be rechallenged with this drug
- Cross-hypersensitivity between ABRAXANE and other taxane products has been reported and may include severe reactions such as anaphylaxis. Patients with a previous history of hypersensitivity to other taxanes should be closely monitored during initiation of ABRAXANE therapy

Hepatic Impairment
- Because the exposure and toxicity of paclitaxel can be increased with hepatic impairment, administration of ABRAXANE in patients with hepatic impairment should be performed with caution
- Patients with hepatic impairment may be at an increased risk of toxicity, particularly from myelosuppression, and should be monitored for development of profound myelosuppression
- For MBC and NSCLC, the starting dose should be reduced for patients with moderate or severe hepatic impairment
- For pancreatic adenocarcinoma, ABRAXANE is not recommended for patients with moderate

  to severe hepatic impairment (total bilirubin >1.5 x ULN and AST ≤10 x ULN)

Albumin (Human)
- ABRAXANE contains albumin (human), a derivative of human blood

Embryo Fetal Toxicity
- Based on mechanism of action and findings in animals, ABRAXANE can cause fetal harm when administered to a pregnant woman
- Advise females of reproductive potential of the potential risk to a fetus.
- Advise females of reproductive potential to use effective contraception and avoid becoming pregnant during treatment with ABRAXANE and for at least six months after the last dose of ABRAXANE
- Advise male patients with female partners of reproductive potential to use effective contraception and avoid fathering a child during treatment with ABRAXANE and for at least three months after the last dose of ABRAXANE

ADVERSE REACTIONS
Randomized Metastatic Breast Cancer (MBC) Study
- The most common adverse reactions (≥20%) with single-agent use of ABRAXANE vs paclitaxel injection in the MBC study are alopecia (90%, 94%), neutropenia (all cases 80%, 82%; severe 9%, 22%), sensory neuropathy (any symptoms 71%, 56%; severe 10%, 2%), abnormal ECG (all patients 60%, 52%; patients with normal baseline 35%, 30%), fatigue/asthenia (any 47%, 39%; severe 8%, 3%), myalgia/arthralgia (any 44%, 49%; severe 8%, 4%), AST elevation (any 39%, 32%), alkaline phosphatase elevation (any 36%, 31%), anemia (any 33%, 25%; severe 1%, <1%), nausea (any 30%, 22%; severe 3%, <1%), diarrhea (any 27%, 15%; severe <1%, 1%) and infections (24%, 20%), respectively
- Sensory neuropathy was the cause of ABRAXANE discontinuation in 7/229 (3%) patients
- Other adverse reactions of note with the use of ABRAXANE vs paclitaxel injection included vomiting (any 18%, 10%; severe 4%, 1%), fluid retention (any 10%, 8%; severe 0%, <1%), mucositis (any 7%, 6%; severe <1%, 0%), hepatic dysfunction (elevations in bilirubin 7%, 7%), hypersensitivity reactions (any 4%, 12%; severe 0%, 2%), thrombocytopenia (any 2%, 3%; severe <1%, <1%), neutropenic sepsis (<1%, <1%), and injection site reactions (<1%, 1%), respectively. Dehydration and pyrexia were also reported
- Renal dysfunction (any 11%, severe 1%) was reported in patients treated with ABRAXANE (n=229)
- In all ABRAXANE-treated patients (n=366), ocular/visual disturbances were reported (any 13%; severe 1%)
- Severe cardiovascular events possibly related to single-agent ABRAXANE occurred in approximately 3% of patients and included cardiac ischemia/infarction, chest pain, cardiac arrest, supraventricular tachycardia, edema, thrombosis, pulmonary thromboembolism, pulmonary emboli, and hypertension
- Cases of cerebrovascular attacks (strokes) and transient ischemic attacks have been reported

Non–Small Cell Lung Cancer (NSCLC) Study

- The most common adverse reactions (≥20%) of ABRAXANE in combination with carboplatin are anemia, neutropenia, thrombocytopenia, alopecia, peripheral neuropathy, nausea, and fatigue
- The most common serious adverse reactions of ABRAXANE in combination with carboplatin for NSCLC are anemia (4%) and pneumonia (3%)
- The most common adverse reactions resulting in permanent discontinuation of ABRAXANE are neutropenia (3%), thrombocytopenia (3%), and peripheral neuropathy (1%)
- The most common adverse reactions resulting in dose reduction of ABRAXANE are neutropenia (24%), thrombocytopenia (13%), and anemia (6%)
- The most common adverse reactions leading to withholding or delay in ABRAXANE dosing

  are neutropenia (41%), thrombocytopenia (30%), and anemia (16%)
- The following common (≥10% incidence) adverse reactions were observed at a similar incidence in ABRAXANE plus carboplatin–treated and paclitaxel injection plus carboplatin– treated patients: alopecia (56%), nausea (27%), fatigue (25%), decreased appetite (17%), asthenia (16%), constipation (16%), diarrhea (15%), vomiting (12%), dyspnea (12%), and rash (10%); incidence rates are for the ABRAXANE plus carboplatin treatment group
- Adverse reactions with a difference of ≥2%, Grade 3 or higher, with combination use of ABRAXANE and carboplatin vs combination use of paclitaxel injection and carboplatin in NSCLC are anemia (28%, 7%), neutropenia (47%, 58%), thrombocytopenia (18%, 9%), and peripheral neuropathy (3%, 12%), respectively
- Adverse reactions with a difference of ≥5%, Grades 1-4, with combination use of ABRAXANE and carboplatin vs combination use of paclitaxel injection and carboplatin in NSCLC are anemia (98%, 91%), thrombocytopenia (68%, 55%), peripheral neuropathy (48%, 64%), edema peripheral (10%, 4%), epistaxis (7%, 2%), arthralgia (13%, 25%), and myalgia (10%, 19%), respectively
- Neutropenia (all grades) was reported in 85% of patients who received ABRAXANE and carboplatin vs 83% of patients who received paclitaxel injection and carboplatin

Pancreatic Adenocarcinoma Study

- Among the most common (≥20%) adverse reactions in the phase III study, those with a ≥5% higher incidence in the ABRAXANE/gemcitabine group compared with the gemcitabine group are neutropenia (73%, 58%), fatigue (59%, 46%), peripheral neuropathy (54%, 13%), nausea (54%, 48%), alopecia (50%, 5%), peripheral edema (46%, 30%), diarrhea (44%, 24%), pyrexia (41%, 28%), vomiting (36%, 28%), decreased appetite (36%, 26%), rash (30%, 11%), and dehydration (21%, 11%)
- Of these most common adverse reactions, those with a ≥2% higher incidence of Grade 3-4 toxicity in the ABRAXANE/gemcitabine group compared with the gemcitabine group, respectively, are neutropenia (38%, 27%), fatigue (18%, 9%), peripheral neuropathy (17%, 1%), nausea (6%, 3%), diarrhea (6%, 1%), pyrexia (3%, 1%), vomiting (6%, 4%), decreased appetite (5%, 2%), and dehydration (7%, 2%)
- Thrombocytopenia (all grades) was reported in 74% of patients in the ABRAXANE/gemcitabine group vs 70% of patients in the gemcitabine group
- The most common serious adverse reactions of ABRAXANE (with a ≥1% higher incidence) are pyrexia (6%), dehydration (5%), pneumonia (4%), and vomiting (4%)
- The most common adverse reactions resulting in permanent discontinuation of ABRAXANE were peripheral neuropathy (8%), fatigue (4%), and thrombocytopenia (2%)
- The most common adverse reactions resulting in dose reduction of ABRAXANE are neutropenia (10%) and peripheral neuropathy (6%)
- The most common adverse reactions leading to withholding or delay in ABRAXANE dosing are neutropenia (16%), thrombocytopenia (12%), fatigue (8%), peripheral neuropathy (15%), anemia (5%), and diarrhea (5%)
- Other selected adverse reactions with a ≥5% higher incidence for all-grade toxicity in the ABRAXANE/gemcitabine group compared to the gemcitabine group, respectively, are asthenia (19%, 13%), mucositis (10%, 4%), dysgeusia (16%, 8%), headache (14%, 9%), hypokalemia (12%, 7%), cough (17%, 7%), epistaxis (15%, 3%), urinary tract infection (11%, 5%), pain in extremity (11%, 6%), arthralgia (11%, 3%), myalgia (10%, 4%), and depression (12%, 6%)
- Other selected adverse reactions with a ≥2% higher incidence for Grade 3-4 toxicity in the ABRAXANE/gemcitabine group compared to the gemcitabine group are thrombocytopenia (13%, 9%), asthenia (7%, 4%), and hypokalemia (4%, 1%)

Postmarketing Experience With ABRAXANE and Other Paclitaxel Formulations

- Severe and sometimes fatal hypersensitivity reactions have been reported with ABRAXANE. The use of ABRAXANE in patients previously exhibiting hypersensitivity to paclitaxel injection or human albumin has not been studied. In postmarketing experience, cross-hypersensitivity

  between ABRAXANE and other taxanes has been reported
- There have been reports of congestive heart failure, left ventricular dysfunction, and atrioventricular block with ABRAXANE, primarily among individuals with underlying cardiac history or prior exposure to cardiotoxic drugs
- There have been reports of extravasation of ABRAXANE. Given the possibility of extravasation, it is advisable to monitor closely the ABRAXANE infusion site for possible infiltration during drug administration

DRUG INTERACTIONS

- Caution should be exercised when administering ABRAXANE concomitantly with medicines known to inhibit or induce either CYP2C8 or CYP3A4

USE IN SPECIFIC POPULATIONS

Pregnancy

- Based on the mechanism of action and findings in animals, ABRAXANE can cause fetal harm when administered to a pregnant woman. Advise females of the potential risk to a fetus and to avoid becoming pregnant while receiving ABRAXANE

Lactation

- Paclitaxel and/or its metabolites were excreted into the milk of lactating rats. Nursing must be discontinued when receiving treatment with ABRAXANE and for two weeks after the last dose

Females and Males of Reproductive Potential

- Females of reproductive potential should have a pregnancy test prior to starting treatment with ABRAXANE
- Advise females of reproductive potential to use effective contraception and avoid becoming pregnant during treatment with and for at least six months after the last dose of ABRAXANE *[see Warnings and Precautions]*
- Advise males with female partners of reproductive potential to use effective contraception and avoid fathering a child during treatment with ABRAXANE and for at least three months after the last dose of ABRAXANE *[see Warnings and Precautions]*
- Based on findings in animals, ABRAXANE may impair fertility in females and males of reproductive potential

Pediatric

- The safety and effectiveness of ABRAXANE in pediatric patients have not been evaluated

Geriatric

- A higher incidence of epistaxis, diarrhea, dehydration, fatigue, and peripheral edema was found in patients 65 years or older who received ABRAXANE for MBC in a pooled analysis of clinical studies
- Myelosuppression, peripheral neuropathy, and arthralgia were more frequent in patients ≥65 years of age treated with ABRAXANE and carboplatin in NSCLC
- Diarrhea, decreased appetite, dehydration, and epistaxis were more frequent in patients 65 years or older compared with patients younger than 65 years old who received ABRAXANE and gemcitabine in adenocarcinoma of the pancreas

Renal Impairment

- There are insufficient data to permit dosage recommendations in patients with severe renal impairment or end stage renal disease (estimated creatinine clearance <30 mL/min)

DOSAGE AND ADMINISTRATION

- Do not administer ABRAXANE to any patient with total bilirubin greater than 5 x ULN or AST greater than 10 x ULN

- For MBC and NSCLC, reduce starting dose in patients with moderate to severe hepatic impairment
- For adenocarcinoma of the pancreas, do not administer ABRAXANE to patients who have moderate to severe hepatic impairment
- Dose reductions or discontinuation may be needed based on severe hematologic, neurologic, cutaneous, or gastrointestinal toxicity
- Monitor patients closely

Please see full Prescribing Information, including Boxed WARNING.

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 approximately 2,400 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® (nanoparticle albumin–bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) in China under a license from Celgene Corporation.

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 advancement of, and anticipated development, regulatory milestones and commercialization of ABRAXANE. 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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BeiGene, Ltd.

BeiGene Announces Clinical Results from Three Posters on Zanubrutinib Presented at the 24th Congress of European Hematology Association (EHA)

First Preliminary Data from Exploratory MYD88^{WT} Patient Cohort in Phase 3 Trial in Waldenström's Macroglobulinemia (WM)*; Updated Phase 1/2 WM Data; and Pooled Safety Data Analysis on Zanubrutinib in B-Cell Malignancies Presented*

Company to Host Investor Conference Call and Webcast of Mid-2019 Clinical Data Updates on Thursday, June 20, 2019 at 8:00 a.m. EDT

CAMBRIDGE, Mass. and BEIJING, China, June 14, 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 announced the first presentation of clinical results from the ASPEN trial, a global randomized Phase 3 open-label trial of its investigational BTK inhibitor zanubrutinib in patients with Waldenström's Macroglobulinemia (WM). The poster presentation included clinical results from a nonrandomized exploratory cohort of patients with the MYD88^{WT} genotype of WM. In addition, BeiGene announced updated results from the ongoing Phase 1/2 trial of patients with WM; and a pooled safety data analysis of zanubrutinib from six ongoing monotherapy studies in patients with B-cell malignancies. These data were presented in three posters at the 24th European Hematology Association (EHA) Congress, taking place June 13-16 in Amsterdam.

"We are excited to announce new data from ongoing zanubrutinib clinical studies at EHA, including the first results of the Phase 3 ASPEN trial from a non-randomized cohort of patients who have WM with the MYD88^{WT} genotype. For these patients, who typically have poorer prognoses with lower response rates, we recognize the real need for a highly potent and selective BTK inhibitor that can sustain BTK inhibition and reduce off-target effects. We are excited that these data have echoed what we saw in earlier trials, with an overall response rate of 81 percent and a major response rate that includes patients with a partial response or better, of 54% including 23% with a very good partial response (VGPR)," said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. "We will continue to follow these patients to further assess outcomes. Full results from the trial are planned for presentation at a medical congress later this year."

Dr. Huang continued, "In addition, with longer follow-up from the global Phase 1/2 trial of zanubrutinib in patients with WM, we're seeing high rates of CR/VGPR (42%) that are proving to be durable responses. Separately, the pooled safety data analysis of zanubrutinib continues to affirm its tolerability as a selective BTK inhibitor, in patients with B-cell malignancies. We believe that these data further support zanubrutinib's potential to become a meaningful treatment option for patients with B-cell malignancies around the world."

Major Responses in Patients with MYD88 Wildtype WM Treated with Zanubrutinib

Abstract Number: PF487

The ASPEN trial, a randomized open-label, multicenter Phase 3 trial (clinicaltrials.gov Identifier: NCT03053440) of zanubrutinib vs. ibrutinib in patients with WM, has enrolled 26 patients who were centrally determined at study entry to have the MYD88^{WT} genotype. These patients were enrolled in the non-randomized cohort and assigned to receive zanubrutinib 160mg twice daily (BID). Responses were assessed using modified IWWM-6 criteria with endpoints of combined rate of complete response (CR) and very good partial response (VGPR), overall response rate (ORR), major response rate (MRR) and safety.

This exploratory analysis included five patients with treatment-naïve (TN) disease and 21 patients with relapsed/refractory (R/R) WM.

As of February 28, 2019, the median follow-up was 12.2 months (range 2.3 – 21.7 months) and 17 patients remained on study. Results included:

- The ORR was 80.8%. MRR (partial response or better) was 53.8% and the VGPR rate was 23.1%. One patient achieved a complete response by IgM criteria with normal IgM levels and negative immunofixation;
- Median time to first major response (partial response or better) was 2.9 months;
- Median progression-free survival (PFS) and overall survival (OS) have not yet been reached;
- Zanubrutinib tolerability was generally consistent with previous reports. Discontinuation due to adverse events (AEs) occurred in 7.7% of patients (n=2). The primary reason for discontinuation was progressive disease;
- The most common AEs (in >15% pts) were diarrhea (19%), hypertension (19%), contusion (15%), constipation (15%), muscle spasm (15%), pneumonia (15%), and upper respiratory tract infection (15%);
- There were no fatal AEs or atrial fibrillation/flutter events reported; and
- Among adverse events of special interest for BTK inhibitors, bleeding was observed in nine patients (34.6%), hypertension was observed in five patients (19.2%), Grade 3 or 4 cytopenias were observed in four patients (15.4%), Grade 3 or 4 infections were observed in three patients (11.5%), and secondary malignancy in three patients (11.5%). Two patients had major hemorrhage (7.7%).

“Zanubrutinib is a highly potent and selective BTK inhibitor with good bioavailability that was generally well-tolerated in this exploratory cohort from the Phase 3 ASPEN trial, said Meletios A. Dimopoulos, M.D., Professor of Hematology and Medical Oncology, Chairman of the Department of Clinical Therapeutics, Rector of the National and Kapodistrian University of Athens, Greece and first author on the poster. “For the patients with wildtype MYD88 genotype, we are excited by these data that support the results we’ve seen previously from Phase 1/2 studies.”

Summary of Updated Clinical Results From the Global Phase 1/2 Trial

Abstract Number PF481

This global, open-label Phase 1/2 trial (clinicaltrials.gov identifier: NCT02343120) of zanubrutinib as monotherapy in patients with B-cell malignancies, including a cohort of patients with WM, is being conducted in Australia, New Zealand, the United States, Italy, the United Kingdom and South Korea. As of September 16, 2018, 77 patients with TN (n=24) or R/R (n=53) WM without prior BTK exposure have been enrolled in the trial; the median follow-up time was 23.9 months (4.4-45.7). Seventy-three patients including 24 with TN and 49 with R/R WM, were evaluable for efficacy in this analysis, per modified IWWM-6 criteria. At the time of the data cutoff, 61 patients remained on study treatment. Updated results included:

- The ORR by independent review committee (IRC) was 92% (67/73) including MRR of 82% (60/73) and CR / VGPR rate of 42% (31/73).
- The estimated PFS rate at 12 and 24 months was 90% and 81%, respectively;
- Zanubrutinib tolerability was generally consistent with previous reports in patients with various B-cell malignancies and AEs were predominantly grade 1 or 2 in severity. The most frequent AEs were upper respiratory tract infection (46%), contusion (30%), cough (20%), headache (18%) and diarrhea (17%);
- Grade 3-4 AEs occurred in 51.9% of patients. Grade 3-4 AEs of any attribution reported in > 3 patients included neutropenia (10%); anemia (7.8%), basal cell carcinoma (5%) and hypertension (5%); and
- With a median follow up 24 months, discontinuation due to AEs occurred in 10.4% of patients, with five fatal events.

“As we continue to follow the Phase 1/2 trial of zanubrutinib, now for more than four years, we are impressed by the tolerability and efficacy of this BTK inhibitor for patients with WM who had not received prior BTK inhibition therapy,” said

Judith Trotman, MBChB, FRACP, FRCPA, Clinical Professor of Medicine at Concord Repatriation General Hospital, Concord, New South Wales, Australia and first author on the poster.

Pooled Analysis of Safety Data from Monotherapy Studies of Zanubrutinib in B-cell Malignancies

Abstract Number PS1159

Safety results from six ongoing, Phase 1 and Phase 2 clinical trials of zanubrutinib monotherapy, including collectively 682 patients with non-Hodgkin's lymphoma (NHL), WM, or chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), were included in this comprehensive analysis. The majority of patients had R/R disease; almost all patients received zanubrutinib at a dose of 320mg once daily or 160mg twice daily. The median duration of zanubrutinib exposure was 13.4 months (0.1-49.7).

This analysis included an evaluation of the frequency and severity of AEs, AEs of Special Interest (AESIs), and AEs leading to death, dose reduction or treatment discontinuation (d/c).

Ninety-seven percent of patients reported at least one AE, which were primarily grade 1 or 2. The most common AEs of all grades included upper respiratory tract infection (32.4%), neutrophil count decreased (25.2%), diarrhea (19.4%), cough (19.1%), contusion (18.6%), and rash (18%). The most common grade ≥3 AEs included neutrophil count decreased (14.4%), anemia (7.6%), neutropenia (6.6%), pneumonia (4.5%), platelet count decreased (4.3%), and lung infection (4.1%). Serious AEs (SAEs) consisting primarily of infectious complications such as pneumonia/lung infection were reported in 36% of patients.

AESIs such as atrial fibrillation/flutter (1.9%), major hemorrhage (2.5%), and grade ≥3 hypertension (3.4%) were infrequent, and treatment discontinuation due to AEs was uncommon (9.1% overall, including 3.5% for whom the event(s) were treatment-related).

"Zanubrutinib was generally well-tolerated, with less than five percent discontinuation for treatment-related adverse events. These data also demonstrated low safety-related treatment failure rates at doses of zanubrutinib associated with complete and sustained BTK inhibition," commented Constantine S. Tam, M.D., Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at Peter MacCallum Cancer Center and Director of Hematology at St. Vincent's Hospital, Australia, and lead author of the poster presentation.

Mid-2019 Clinical Data Update Conference Call and Webcast Information:

BeiGene will host a conference call and webcast on Thursday, June 20 at 8:00 a.m. EDT. Investors and analysts are invited to join the conference call using the following dial-in information:

U.S. Toll-Free: +1 (844) 461-9930
U.S. Toll: +1 (478) 219-0535
Hong Kong Toll-Free: +852 800 279 19250
China Toll-Free: +86 800 914 686
Conference ID: 1790069

A live webcast of the conference call can be accessed from the investors section of BeiGene's website at http://ir.beigene.com/ or http://hkexir.beigene.com. An archived replay will be available two hours after the event for 90 days.

About Zanubrutinib

Zanubrutinib (BGB-3111) is an investigational small molecule inhibitor of Bruton's tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated in a broad pivotal clinical program globally as a monotherapy and in combination with other therapies to treat various B-cell malignancies.

Clinical trials of zanubrutinib include a fully-enrolled, global Phase 3 clinical trial in patients with Waldenström macroglobulinemia (WM) comparing zanubrutinib to ibrutinib, currently the only approved BTK inhibitor for WM; a global Phase 3 clinical trial in patients with previously untreated chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL); a pivotal Phase 2 trial in patients with relapsed/refractory (R/R) follicular lymphoma in combination with

GAZYVA® (obinutuzumab); a Phase 3 trial comparing zanubrutinib to ibrutinib in patients with R/R CLL/SLL; and a global Phase 1 trial. In China, BeiGene has completed two pivotal Phase 2 clinical trials of zanubrutinib in patients with MCL and CLL/SLL and the enrollment in the pivotal Phase 2 clinical trials in patients with WM.

Zanubrutinib has been granted by the U.S. Food and Drug Administration (FDA) Fast Track designation for the treatment of patients with WM, and Breakthrough Therapy designation for the treatment of adult patients with MCL who have received at least one prior therapy. The New Drug Applications (NDAs) in China for R/R MCL and R/R CLL/SLL have been accepted by the China National Medical Products Administration (NMPA) and granted priority review. BeiGene plans to submit its first NDA in the U.S. for zanubrutinib in 2019 or early 2020.

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 approximately 2,400 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® (nanoparticle albumin–bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) in China under a license from Celgene Corporation.

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 zanubrutinib and BeiGene’s advancement of, and anticipated clinical development, regulatory milestones and commercialization of zanubrutinib. 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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BeiGene Announces Updated Results from a Pivotal Phase 2 Study of Tislelizumab in Chinese Patients with Relapsed or Refractory Classical Hodgkin Lymphoma at the 24th Congress of the European Hematology Association (EHA)

Company to Host Investor Conference Call and Webcast of Mid-2019 Clinical Data Updates on Thursday, June 20 at 8:00 a.m. EDT

CAMBRIDGE, Mass. and BEIJING, China; June 14, 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 announced updated results from a pivotal Phase 2 study of tislelizumab, an investigational anti-PD-1 antibody, in Chinese patients with relapsed/refractory (R/R) classical Hodgkin lymphoma (cHL) in a poster at the 24th Congress of the European Hematology Association (EHA), taking place June 13-16, 2019 in Amsterdam.

“The encouraging clinical results from this study further support our new drug application for tislelizumab in patients with R/R cHL that is currently under priority review in China,” said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. “We hope that this potentially differentiated anti-PD-1 antibody could become a new treatment option for cancer patients in China and across the world.”

“Tislelizumab demonstrated high anti-tumor activity in patients with R/R cHL – evidenced by an overall response rate of 87% and a complete response rate of 63%, and was generally well tolerated in these patients,” said Yuqin Song, M.D., Ph.D., Associate Professor of Medical Oncology, Deputy Director of the Lymphoma Department at Peking University Cancer Hospital in China, and the presenting author of the study.

Summary of Clinical Results

Abstract Number: PF469

This single-arm, multi-center, pivotal Phase 2 study of tislelizumab as a monotherapy in Chinese patients with R/R cHL (clinicaltrials.gov identifier: NCT03209973) enrolled 70 patients who were either R/R to autologous stem cell transplantation (ASCT), or received at least two prior lines of systemic therapy for cHL and were not candidates for ASCT. Patients were treated with tislelizumab, dosed at 200 mg intravenously every three weeks. The primary endpoint of the trial is overall response rate (ORR) assessed by independent review committee (IRC) according to the Lugano Classification 2014.

As of November 26, 2018, 70 patients with R/R cHL were evaluable for efficacy. Thirteen patients received prior ASCT, and the remaining 57 patients were ineligible for ASCT. Patients had a median of three prior lines of systemic therapy (2-11). Results included:

- With a minimum of 23.8 weeks of follow-up and a median follow-up time of 13.9 months at the data cutoff, the ORR by IRC was 87.1% (61/70); 44 patients (62.9%) achieved a complete response (CR), and 17 patients (24.3%) achieved a partial response (PR);
- The median duration of response (DOR) has not been reached;
- Twelve-month progression-free survival (PFS) was estimated at 73.8% and median PFS has not been reached;

- The majority of adverse events (AEs) were grade 1 or 2 in severity. The most frequently reported treatment-emergent adverse events (TEAEs) of any grade include pyrexia (57.1%), weight increase (34.3%), upper respiratory tract infection and hypothyroidism (32.9% each), pruritus, white blood cell (WBC) count decreased, and cough (18.6%, each);
- Grade ≧3 TEAEs occurred in 30% of patients, with the most frequently reported being hypertension, pneumonitis, neutrophil count decrease, upper respiratory tract infection, and weight increase (2.9%, each); only 2.9% of patients reported grade 4 TEAEs and there were no fatal TEAEs.
- Four patients (5.7%) discontinued treatment due to TEAEs, including pneumonitis (n=2), focal segmental glomerulosclerosis (n=1), and organizing pneumonia (n=1); and
- Immune-related (ir) TEAEs reported in more than 5% of patients included thyroid disorder (22.9%), skin adverse reactions (8.6%)*, and pneumonitis (7.1%).

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About Classical Hodgkin Lymphoma

Hodgkin's lymphoma is one of the two major types of lymphoma that begin in the lymph nodes and tissues of the lymphatic system. All other lymphomas are classified as non-Hodgkin's lymphomas. Classical Hodgkin lymphoma, the most common form representing about 95% of patients with Hodgkin's lymphoma, is characterized by the presence of very large cells called Reed-Sternberg cells. There were approximately 2,100 diagnosed cases of Hodgkin's lymphoma in China in 2012. Although the cancer can occur in both children and adults, it is most commonly diagnosed in young adults between the ages of 15 and 35 and in older adults over age 50.

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. Tislelizumab is the first drug candidate produced from BeiGene's immuno-oncology biologic 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 being studied in a broad clinical program. BeiGene has completed a pivotal Phase 2 clinical trial in patients with relapsed or refractory (R/R) classical Hodgkin's lymphoma (cHL). Ongoing clinical trials of tislelizumab include a Phase 3 clinical trial in patients with second-line or third-line non-small cell lung cancer (NSCLC); a Phase 3 clinical trial in first-line patients with hepatocellular carcinoma (HCC); a Phase 3 clinical trial in second-line patients with esophageal squamous carcinoma (ESCC); a Phase 3 clinical trial in first-line patients with gastric cancer (GC); a Phase 3 clinical trial in first-line patients with ESCC; a Phase 3 trial in patients with Stage III NSCLC; a Phase 2 clinical trial in second- or third-line patients with HCC; and a Phase 2 clinical trial in patients with R/R NK/T-cell lymphomas. The aforementioned studies are enrolling patients in multiple countries, including the U.S., Europe, and China.

Additionally, BeiGene is conducting a Phase 3 clinical trial in first-line patients with non-squamous NSCLC; a Phase 3 clinical trial in first-line patients with squamous NSCLC; a Phase 3 clinical trial in patients with nasopharyngeal cancer (NPC); a Phase 3 clinical trial in first-line patients with urothelial carcinoma (UC); a pivotal Phase 2 clinical trial in patients with locally advanced or metastatic UC; and a pivotal Phase 2 trial in patients with MSI-H or dMMR solid tumors. These studies are enrolling patients in China.

New drug applications (NDA) for tislelizumab in patients with R/R cHL and in patients with previously treated locally advanced or metastatic UC have been accepted by the China National Medical Products Administration (NMPA, formerly known as CFDA) and the R/R cHL filing has been granted priority review. BeiGene and Celgene Corporation have a global strategic collaboration for the development of tislelizumab in solid tumor cancers outside of Asia (except Japan).

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