
**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, 2017**

BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction
of incorporation)

001-37686
(Commission File Number)

98-1209416
(I.R.S. Employer Identification No.)

**c/o Maurant 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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 8.01 Other Events

On June 14, 2017, BeiGene, Ltd. (the “Company”) issued a press release announcing updated clinical data from the ongoing Phase 1 trial of its Bruton’s Tyrosine Kinase (“BTK”) inhibitor BGB-3111 in patients with chronic lymphocytic leukemia (“CLL”) and small lymphocytic lymphoma (“SLL”) in a poster at the 14th International Conference on Malignant Lymphoma (“14-ICML”) in Lugano, Switzerland. The full text of the Company’s press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On June 15, 2017, the Company issued a press release announcing updated data from the ongoing Phase 1 trial of its BTK inhibitor BGB-3111 in patients with Waldenström’s macroglobulinemia presented at 14-ICML. The full text of the Company’s press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

On June 16, 2017, the Company issued a press release announcing initial clinical data from the ongoing Phase 1 trial of its BTK inhibitor BGB-3111 combined with the anti-CD20 antibody obinutuzumab in patients with CLL or SLL and follicular lymphoma presented at 14-ICML. The full text of the Company’s press release is filed as Exhibit 99.3 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 issued on June 14, 2017
99.2	Press Release issued on June 15, 2017
99.3	Press Release issued on June 16, 2017

* * *

SIGNATURES

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.

Date: June 16, 2017

BEIGENE, LTD.

By:	<u>/s/ Scott A. Samuels</u>
Name:	Scott A. Samuels
Title:	Senior Vice President, General Counsel

Exhibit Index

Exhibit No.	Description
99.1	Press Release issued on June 14, 2017
99.2	Press Release issued on June 15, 2017
99.3	Press Release issued on June 16, 2017



BeiGene Presents Updated Phase 1 Data on BTK Inhibitor BGB-3111 in Patients with Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma at the 14th International Conference on Malignant Lymphoma

CAMBRIDGE, Mass. and BEIJING, China, June 14, 2017 (GLOBE NEWSWIRE) — BeiGene, Ltd. (NASDAQ:BGNE), a clinical-stage biopharmaceutical company developing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer, today presented updated clinical data from an ongoing Phase 1 study of BTK inhibitor BGB-3111 in patients with chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) in a poster at the 14th International Conference on Malignant Lymphoma (14-ICML) in Lugano, Switzerland. The updated Phase 1 data continue to demonstrate that BGB-3111 is well tolerated and highly active in CLL/SLL, with a high overall response rate (94%) and a very low treatment discontinuation rate (3%) at a median follow-up of 10.5 months for efficacy evaluation.

“The updated data demonstrate that BGB-3111 has a high overall response rate in CLL and SLL, independent of poor-risk molecular features. It is also well tolerated, with only a single instance of toxicity-related discontinuation to date. Late-stage trials will further characterize BGB-3111’s clinical benefit and safety in CLL and SLL,” commented John Seymour, MBBS, FRACP, PhD, Director of Cancer Medicine at Peter MacCallum Cancer Centre in Victoria, Australia, and the lead author of the presentation.

“The Phase 1 data on BGB-3111 in CLL and SLL have matured favorably since our last presentation at the 2016 American Society for Hematology Annual Meeting in December 2016. The rate and durability of response suggest that the complete and sustained BTK inhibition achieved with BGB-3111 results in high activity in CLL and SLL patients in the study to date. These results further affirm our plans to develop

this agent for CLL and SLL both in China, where we have an ongoing pivotal trial, and globally,” commented Jane Huang, MD, Chief Medical Officer, Hematology at BeiGene.

Summary of Results from the Ongoing Phase 1 Study

The multi-center, open-label Phase 1 trial of BGB-3111 in patients with B-cell malignancies is being conducted in Australia, New Zealand, South Korea, and the United States and consists of a dose-escalation phase and a dose-expansion phase in disease-specific cohorts, which include treatment naïve (TN) and relapsed/refractory (R/R) CLL/SLL. The ongoing dose-expansion component is testing doses of 160 mg twice a day (BID) or 320 mg once a day (QD). As of March 31, 2017, 69 patients with CLL or SLL (18 TN, 51 R/R) were enrolled in the study.

BGB-3111 was shown to be well tolerated in CLL/SLL. The most frequent adverse events (AEs) ($\geq 10\%$) of any attribution were petechiae/purpura/contusion (46%), fatigue (29%), upper respiratory tract infection (28%), cough (23%), diarrhea (22%), headache (19%), hematuria (15%), nausea (13%), rash (13%), arthralgia (12%), muscle spasms (12%), and urinary tract infection (12%); all of these events were grade 1 or 2 except for one case of grade 3 purpura (subcutaneous hemorrhage), which was the only major bleeding event. Additional adverse events of interest included one case of each grade 2 diarrhea and grade 2 atrial fibrillation. A total of 18 serious AEs (SAEs) occurred in 13 patients, with no SAE occurring in more than one patient. Only one patient discontinued treatment due to an AE, a grade 2 pleural effusion.

At the time of the data cutoff, 66 patients (16 TN and 50 R/R) had more than 12 weeks of follow-up and were evaluable for efficacy, and three other patients had less than 12 weeks of follow-up. After a median follow-up of 10.5 months (2.2-26.8 months), the overall response rate (ORR) was 94% (62/66) with complete

responses (CRs) in 3% (2/66), partial responses (PRs) in 82% (54/66), and PRs with lymphocytosis (PR-Ls) in 9% (6/66) of patients. Stable disease (SD) was observed in 5% (3/66) of patients. The patient with pleural effusion discontinued treatment prior to week 12 and was not evaluable for response. There was one instance of Hodgkin's transformation. In TN CLL/SLL, at a median follow-up time of 7.6 months (3.7-11.6 months), the ORR was 100% (16/16) with CRs in 6% (1/16), PRs in 81% (13/16) and PR-Ls in 13% (2/16) of patients. In R/R CLL/SLL, at a median follow-up time of 14.0 months (2.2-26.8 months), the ORR was 92% (46/50) with CRs in 2% (1/50), PRs in 82% (41/50), and PR-Ls in 8% (4/50) of patients. Stable disease was observed in 6% (3/50) patients.

Investor Call and Webcast Information

BeiGene will host an investor call and webcast to discuss the data presented at 14-ICML and its development program.

Date & Time: Friday, June 16, 2017, 2:00 PM CEST (8:00 AM EDT, 8:00 PM China Standard Time)

Dial-in Numbers: 1-845-675-0437 or 1-866-519-4004 (US), 400-620-8038 or 800-819-0121 (China), +852 30186771 (Hong Kong), or +65 67135090 (International)

Conference ID Number: 33044427

A live webcast and replay will be available on BeiGene's investor website <http://ir.beigene.com/>. The dial-in replay will be available approximately two hours after the conference and will be available for two days following the event. It can be accessed by dialing 1-646-254-3697 (US), 400-632-2162 (China), +852 30512780 (Hong Kong), or +61 2 8199 0299 (International).

About BGB-3111

BGB-3111 is a potent and highly selective investigational small molecule inhibitor of

BTK (Bruton's Tyrosine Kinase). BGB-3111 has demonstrated higher selectivity against BTK than ibrutinib (the only BTK inhibitor currently approved by the U.S. Food and Drug Administration and the European Medicines Agency) based on biochemical assays, higher exposure than ibrutinib based on their respective Phase I experience, and sustained 24-hour BTK occupancy in both the blood and the lymph node.

About BeiGene

BeiGene is a global, clinical-stage, research-based biotechnology company focused on molecularly targeted and immuno-oncology cancer therapeutics. With a team of over 400 employees in China, the United States, and Australia, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for the treatment of cancer. BeiGene is working to create combination solutions aimed at having both a meaningful and lasting impact on cancer patients.

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 of BGB-3111 and our future development plans for BGB-3111. 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; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; BeiGene's ability to achieve market acceptance in the medical community necessary for commercial success; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct preclinical studies and clinical trials and manufacturing; 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.

Investor/Media Contact

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BeiGene Presents Updated Phase 1 Data on BTK Inhibitor BGB-3111 in Patients with Waldenström's Macroglobulinemia at the 14th International Conference on Malignant Lymphoma

CAMBRIDGE, Mass. and BEIJING, China, June 15, 2017 (GLOBE NEWSWIRE) — BeiGene, Ltd. (NASDAQ:BGNE), a clinical-stage biopharmaceutical company developing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer, today presented updated data from an ongoing Phase 1 study of Bruton's tyrosine kinase (BTK) inhibitor BGB-3111 in patients with Waldenström's macroglobulinemia (WM) at the 14th International Conference on Malignant Lymphoma (14-ICML) in Lugano, Switzerland. The updated Phase 1 data continue to demonstrate that BGB-3111 is well tolerated, with a very good partial response (VGPR) rate of 43% and with an overall response rate (ORR) of 90% in 42 efficacy-evaluable patients with a median follow-up time of 12.3 months.

"The updated data continue to suggest that BGB-3111 is well tolerated in WM. Particularly notable is the VGPR rate of over 40% in an evaluable population of 42 patients. In addition, responses to BGB-3111 appear to deepen with time and to occur in patients both with and without *MYD88* mutations. The rates of adverse event-related discontinuation and disease progression remain very low," commented Judith Trotman, MBChB, FRACP, FRCPA, Director of Clinical Research in Haematology at the Concord Repatriation General Hospital, Clinical Associate Professor of Medicine at the University of Sydney, and the lead author of the abstract.

"We are very pleased to update our Phase 1 data of BGB-3111 in patients with WM. The high rate of VGPRs observed to date may result in part from BGB-3111's ability to completely and sustainably occupy BTK in both circulating and nodal lymphocytes. The VGPR rate also further supports the continued evaluation of BGB-

3111 in its global, head-to-head Phase 3 study against ibrutinib in WM,” commented Jane Huang, MD, Chief Medical Officer, Hematology at BeiGene.

Summary of Results from the Ongoing Phase 1 Study

The multi-center, open-label Phase 1 trial of BGB-3111 as monotherapy in B-cell malignancies is being conducted in Australia, New Zealand, South Korea, and the United States and consists of a dose-escalation phase and a dose-expansion phase in disease-specific cohorts, which include treatment naïve and relapsed/refractory WM. The ongoing dose-expansion phase is testing doses of 160 mg twice a day (BID) or 320 mg once a day (QD). As of March 31, 2017, 48 patients with WM were enrolled in the study. Responses were determined according to the modified Sixth International Workshop on WM (IWWM) criteria.

BGB-3111 was shown to be well tolerated with no discontinuation for BGB-3111-related toxicity to date. Adverse events (AEs) were generally mild in severity and self-limited. The most frequent AEs (>10%) of any attribution among 48 patients evaluable for safety were petechiae/purpura/contusion (35%), upper respiratory tract infection (31%), constipation (25%), diarrhea (19%), epistaxis (19%), nausea (17%), cough (15%), anemia (15%), headache (15%), neutropenia (13%), and rash (13%), all of which were grade 1 or 2 in severity except for grade 3 or 4 anemia and neutropenia (8% each) as well as grade 3 or 4 diarrhea and headache (2% each). Five serious AEs were assessed to be possibly related to BGB-3111; these included one case each of hemothorax, atrial fibrillation, colitis, febrile neutropenia, and headache. Among AEs of special interest, there were a total of three cases of atrial fibrillation (all grade 1 or 2), and one case of serious hemorrhage (hemothorax), defined as grade 3 or higher hemorrhage or central nervous system hemorrhage of any grade. Three events led to treatment discontinuation: one case each of bronchiectasis, prostate adenocarcinoma, and adenocarcinoma of pylorus.

At the time of the data cutoff, 42 patients were evaluable for response. Patients not evaluable for efficacy included two patients with less than 12 weeks of follow-up, three patients with IgM < 500mg/dl at baseline, and one patient with inaccurate baseline IgM due to cryoprotein. At a median follow-up of 12.3 months (4.4–30.5 months), the ORR was 90% (38/42 patients) and the major response rate was 76% (32/42 patients), with VGPRs in 43% (18/42) of patients and partial responses in 33% (14/42) of patients. There were two cases of disease progression.

Investor Call and Webcast Information

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biochemical assays, higher exposure than ibrutinib based on their respective Phase 1 experience, and sustained 24-hour BTK occupancy in both the blood and the lymph node.

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BeiGene Presents Initial Phase 1 Data on BTK Inhibitor BGB-3111 Combined with Obinutuzumab at the 14th International Conference on Malignant Lymphoma and Announces Additional Planned Global Registrational Trials for BGB-3111

CAMBRIDGE, Mass., and BEIJING, China, June 16, 2017 (GLOBE NEWSWIRE) — BeiGene, Ltd. (NASDAQ:BGNE), a clinical-stage biopharmaceutical company developing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer, today presented initial clinical data from an ongoing Phase 1 trial of the Bruton's Tyrosine Kinase (BTK) inhibitor BGB-3111 combined with the anti-CD20 antibody obinutuzumab in patients with chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) and follicular lymphoma (FL) at the 14th International Conference on Malignant Lymphoma (14-ICML) in Lugano, Switzerland. The initial Phase 1 data demonstrate that the combination is well tolerated with an overall response rate (ORR) of 89% including complete responses (CRs) in 22% of treatment naïve (TN) CLL/SLL patients, an ORR of 92% with CRs in 16% of relapsed/refractory (R/R) CLL/SLL patients, and an ORR of 73% with CRs in 33% of R/R FL patients.

"This clinical trial is supported by preclinical work suggesting that BGB-3111 may combine well with antibodies that rely on antibody-dependent cell-mediated cytotoxicity, such as obinutuzumab, because of less off-target inhibition of interleukin-2-inducible T-cell kinase. The preliminary clinical results to date suggest that the combination is well tolerated and highly active in patients with CLL or SLL and FL. Complete responses have already been observed in patients with both disease types, including CLL or SLL patients with high-risk features, despite a very short follow-up time," commented Constantine Tam, MD, Disease Group Lead for Low Grade Lymphoma and Chronic Lymphocytic Leukemia at Peter MacCallum Cancer Centre, Director of Haematology at St. Vincent's Hospital, Australia, and lead author of the presentation.

“We are very pleased to report initial results from our first combination trial with BGB-3111. The preliminary complete response rate in CLL and SLL, as well as the frequency and depth of responses in FL, appear to be favorable compared to reported data with BTK inhibitors or anti-CD20 antibodies alone. Given the depth and durability of BGB-3111 monotherapy activity in our trials to date, we look forward to seeing the combination data mature over time and plan to initiate late-stage trials of this combination in FL,” commented Jane Huang, MD, Chief Medical Officer, Hematology at BeiGene.

On the basis of data presented on BGB-3111, BeiGene announced that it plans to expand its global registrational program for BGB-3111 to include a Phase 2 pivotal trial of BGB-3111 in combination with obinutuzumab compared to obinutuzumab alone in patients with R/R FL. In addition, based on data with BGB-3111 monotherapy presented earlier at this meeting, BeiGene is planning to initiate a Phase III trial comparing BGB-3111 with bendamustine plus rituximab in patients with TN CLL. These two additional trials will expand the late-stage clinical trial program for BGB-3111, which includes an ongoing global Phase 3 comparison trial with ibrutinib in Waldenström’s macroglobulinemia (WM) and single-arm pivotal trials in R/R CLL/SLL and R/R mantle cell lymphoma intended to support approval of BGB-3111 in China.

Summary of Results from the Ongoing Phase 1 Trial

The multi-center, open-label Phase 1 trial of BGB-3111 with obinutuzumab in patients with B-cell malignancies is being conducted in Australia and the United States and consists of a dose-escalation phase and a dose-expansion phase in disease-specific cohorts, which include TN or R/R CLL/SLL and R/R FL. The dose-escalation component is testing BGB-3111 at 320 mg once daily (QD) or 160 mg twice daily (BID) in 28-day cycles, in combination with obinutuzumab; obinutuzumab was administered in line with standard CLL dosing (three loading doses of 1000 mg

weekly followed by 1000 mg on day one of cycles 2—6). The ongoing dose-expansion component is testing doses of BGB-3111 at 160 mg BID with the same obinutuzumab schedule. As of March 31, 2017, 45 patients with CLL/SLL and 17 patients with FL were enrolled in the trial.

At the time of the data cutoff of March 31, 2017, BGB-3111 was shown to be well tolerated in both CLL/SLL and FL. The most frequent adverse events (AEs) ($\geq 15\%$) of any attribution in CLL/SLL were petechiae/purpura/contusion (33%), neutropenia (31%), thrombocytopenia (22%), fatigue (18%), pyrexia (18%), upper respiratory tract infection (18%), and diarrhea (16%); all of these were grade 1 or 2 except for grade 3 or 4 neutropenia (20%) and grade 3 or 4 thrombocytopenia (4%). The most frequent AEs ($\geq 15\%$) in FL were petechiae/purpura/contusion (35%), fatigue (29%), cough (18%), diarrhea (18%), dizziness (18%), headache (18%), insomnia (18%), nausea (18%), and upper respiratory tract infection (18%); all of these were grade 1 or 2. Serious AEs occurred in 24% of both the CLL/SLL and FL patients. Infusion-related reactions occurred in 24% of CLL/SLL patients and 6% of FL patients; all cases were grade 1 or 2 except for one grade 4 case in a CLL/SLL patient. There were no cases of serious hemorrhage (\geq grade 3 hemorrhage or central nervous system hemorrhage of any grade) or atrial fibrillation. Only one patient discontinued treatment due to an AE, squamous cell carcinoma (SCC), and this patient had a prior history of SCC.

At the time of the data cutoff, 43 patients with CLL/SLL (18 TN, 25 R/R) and 15 patients with R/R FL had greater than 12 weeks of follow-up and were evaluable for efficacy. In TN CLL/SLL, after a median follow-up of 7.0 months (2.8—11.8 months), the overall response rate (ORR) was 89% with complete responses (CRs) in 22% and partial responses (PRs) in 67% of patients. Stable disease (SD) was observed in 11% of patients. In R/R CLL/SLL, at a median follow-up time of 8.0 months (3.8—14.0 months) the ORR was 92% with CRs in 16% and PRs in 76% of patients. SD was observed in 4% of patients. In R/R FL, at a median follow-up time of 6.2 months



(1.2—10.7 months), the ORR was 73% with CRs in 33% and PRs in 40% of patients. Stable disease was observed in 13% of patients. One patient with R/R CLL/SLL had progressive disease (Richter's transformation), and two patients with R/R FL had progressive disease.

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