
**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): February 5, 2018

BEIGENE, LTD.

(Exact Name of Registrant as Specified in Charter)

Cayman Islands

(State or Other Jurisdiction of Incorporation)

001-37686

(Commission File Number)

98-1209416

(I.R.S. Employer Identification Number)

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 (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 8.01. Other Events.

On February 5, 2018, BeiGene, Ltd. (the “Company”) issued a press release announcing the commercial availability of VIDAZA[®] (azacitidine for injection) in China. VIDAZA is a nucleoside metabolic inhibitor and was approved in China for patients with Intermediate-2 / High-risk myelodysplastic syndrome (MDS), acute myeloid leukemia (AML) with 20-30% bone marrow blasts and chronic myelomonocyte leukemia (CMML). It is marketed in China by BeiGene under an exclusive license from Celgene Corporation. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on February 5, 2018

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on February 5, 2018

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: February 6, 2018

By: /s/ Scott A. Samuels

Scott A. Samuels

Senior Vice President, General Counsel

BeiGene Announces Commercial Availability of VIDAZA® (Azacitidine for Injection) in China

BEIJING, China, and CAMBRIDGE, Mass., Feb. 05, 2018 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ:BGNE), 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 commercial availability of VIDAZA® (azacitidine for injection) in China. VIDAZA is a nucleoside metabolic inhibitor and was approved in China for patients with Intermediate-2 / High-risk myelodysplastic syndrome (MDS), acute myeloid leukemia (AML) with 20-30% bone marrow blasts and chronic myelomonocyte leukemia (CMML). It is marketed in China by BeiGene under an exclusive license from Celgene Corporation.

“VIDAZA is the only approved hypomethylating agent shown to prolong survival for patients with MDS, and the first new treatment for MDS patients approved in China since 2009. It is the third approved therapy in our commercial portfolio in China, which we plan to further expand in the coming years. We are excited to announce that the first prescription was made in January 2018. From now on, Chinese patients can benefit from VIDAZA in hospitals around China,” commented John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene.

VIDAZA is recommended by National Comprehensive Cancer Network (NCCN) Guidelines in the U.S. as a front-line treatment. In a global Phase 3 trial (AZA-001) involving Intermediate-2 and High risk MDS patients, VIDAZA significantly prolonged the median overall survival to 24.5 months compared with 15 months for the conventional care regimens (CCR- best supportive care, low-dose cytarabine and intensive chemotherapy) group. In the VIDAZA group, 45% of patients who were dependent on red blood cell transfusions at baseline became transfusion independent compared with 11% in the CCR group. There was a higher objective response rate among patients treated with VIDAZA (49%) as compared to the CCR arm (29%). VIDAZA also delayed the onset of AML for these patients (17.8 months vs. 11.5 months). The most common grade 3–4 events were peripheral blood cytopenias for all treatments.

About Myelodysplastic Syndrome, Acute Myeloid Leukemia and Chronic Myelomonocyte Leukemia

MDS is a heterogeneous group of diseases characterized by bone marrow failure and one or more myelodysplasia. In about one-third of patients with MDS, the disease can progress to a rapidly growing cancer of bone marrow cells called AML.ⁱ CMML is a type of cancer that starts in blood-forming cells of the bone marrow and invades the blood; it affects mainly older adults. CMML has features of both MDS and myeloproliferative disorder and is considered the most common disease among myelodysplastic/myeloproliferative diseases.ⁱⁱ

About VIDAZA® (Azacitidine for Injection)

VIDAZA is a nucleoside metabolic inhibitor indicated in China for the treatment of patients with intermediate-2 / high-risk MDS, AML with 20-30% bone marrow blasts and CMML. It is marketed in China by BeiGene under an exclusive license from Celgene Corporation.

In the U.S. VIDAZA is indicated for the treatment of patients with the following FAB MDS subtypes: refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS) (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and CMML.

Important Safety Information

VIDAZA is contraindicated in patients with a known hypersensitivity to azacitidine or mannitol and in patients with advanced malignant hepatic tumors.

In Study 1 (a randomized, open-label, controlled trial carried out in 53 U.S. sites compared the safety and efficacy of subcutaneous VIDAZA plus supportive care with supportive care alone (“observation”) in patients with any of the five FAB subtypes of myelodysplastic syndromes (MDS)) and Study 2 (a multi-center, open-label, single-arm study of 72 patients with RAEB, RAEB-T, CMML, or AML), the most commonly occurring adverse reactions by SC route were nausea (70.5%), anemia (69.5%), thrombocytopenia (65.5%), vomiting (54.1%), pyrexia (51.8%), leukopenia (48.2%), diarrhea (36.4%), injection site erythema (35.0%), constipation (33.6%), neutropenia (32.3%), and ecchymosis (30.5%). Other adverse reactions included dizziness (18.6%), chest pain (16.4%), febrile neutropenia (16.4%), myalgia (15.9%), injection site reaction (13.6%), and malaise (10.9%). In Study 3, the most common adverse reactions by IV route also included petechiae (45.8%), weakness (35.4%), rigors (35.4%), and hypokalemia (31.3%).

In Study 4 (the AZA-001 survival trial), the most commonly occurring adverse reactions were thrombocytopenia (69.7%), neutropenia (65.7%), anemia (51.4%), constipation (50.3%), nausea (48.0%), injection site erythema (42.9%), and pyrexia (30.3%). The most commonly occurring Grade 3/4 adverse reactions were neutropenia (61.1%), thrombocytopenia (58.3%), leukopenia (14.9%), anemia (13.7%), and febrile neutropenia (12.6%).

Because treatment with VIDAZA is associated with anemia, neutropenia and thrombocytopenia, complete blood counts should be performed as needed to monitor response and toxicity, but at a minimum, prior to each dosing cycle.

Because azacitidine is potentially hepatotoxic in patients with severe preexisting hepatic impairment, caution is needed in patients with liver disease. In addition, azacitidine and its metabolites are substantially excreted by the kidneys and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, it may be useful to monitor renal function.

VIDAZA may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be apprised of the potential hazard to the fetus. Men should be advised not to father a child while receiving VIDAZA.

Nursing mothers discontinue nursing or the drug, taking into consideration the importance of the drug to the mother.

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 850 employees in China, the United States, and Australia, 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.ⁱⁱⁱ

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 BeiGene's commercialization of VIDAZA[®] in China, the potential benefits of VIDAZA[®], and BeiGene's plans to commercialize additional drugs in China. 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 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 <https://www.cancer.org/content/dam/CRC/PDF/Public/8743.00.pdf>

ⁱⁱ <https://www.cancer.org/content/dam/CRC/PDF/Public/8689.00.pdf>

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