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

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

Dated October 23, 2018

Commission File Number: 001-38024

BeyondSpring Inc.

BeyondSpring Inc.
28 Liberty Street, 39th Floor
New York, New York 10005
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

On October 23, 2018, BeyondSpring issued press releases relating to its announcement of top line positive efficacy and safety data from Phase 2 Study 106 with its lead asset, Plinabulin, for chemotherapy-induced neutropenia prevention and the use of Plinabulin for the prevention of chemotherapy-induced neutropenia.

Copies of the press releases are attached as Exhibit 99.1 and 99.2 to this report and, except for portions of such exhibits comprised of quotations by BeyondSpring's management, are hereby incorporated by reference into the Registration Statement on Form F-3 (File No. 333-224437) and Registration Statement on Form S-8 (File No. 333-216639).

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, thereunto duly authorized.

BeyondSpring Inc.

By: /s/ Lan Huang

Name: Lan Huang

Title: Chairman and Chief Executive Officer

Date: October 23, 2018

EXHIBIT INDEX

Exhibit No.

Exhibit

[99.1](#)

Press Release, dated October 23, 2018

[99.2](#)

Press Release, dated October 23, 2018

BeyondSpring Announces Top Line Positive Efficacy and Safety Data from Phase 2 Study 106 with Lead Asset, Plinabulin, for Chemotherapy-Induced Neutropenia Prevention

Plinabulin Significantly Reduced Grade 3/4 CIN and Bone Pain When Combined with Neulasta, Compared to Neulasta Monotherapy, in Breast Cancer Patients Receiving High-Risk TAC Chemotherapy

Company to Host Conference Call Today at 8:00 a.m. ET

NEW YORK – October 23, 2018 – **BeyondSpring Inc.** (NASDAQ: BYSI), a global biopharmaceutical company focused on the development of innovative cancer therapies, today announced positive top line Phase 2 data from its Study 106 evaluating Plinabulin in combination with Neulasta® (pegfilgrastim), versus Neulasta monotherapy, for the prevention of chemotherapy-induced neutropenia (CIN) and bone pain in patients receiving high-risk TAC (docetaxel, doxorubicin and cyclophosphamide) chemotherapy. Data collected to-date suggest a significant improvement in efficacy in treating CIN as well as more than a 90 percent reduction in patients experiencing bone pain when adding Plinabulin to the standard of care for the treatment of high-risk CIN.

The current standard of care (G-CSF agents, including Neulasta and filgrastim), although effective against febrile neutropenia, leaves patients at continued risk for grade 3/4 neutropenia, associated mortality and the need to lower chemotherapy dose intensity to sub-optimally effective levels. In addition, these G-CSF agents cause bone pain in the majority of patients, causing patients to refuse further G-CSF treatment and compromising their ability to receive the most effective chemotherapy regimen.

With TAC chemotherapy, the mean Duration of Severe Neutropenia (DSN) continues to exceed 1 day, associated with grade 3/4 CIN frequency of over 90 percent in patients, leading to a delay in TAC dose, dose reduction or switching to less effective chemotherapy regimens.

Plinabulin is a novel, non-G-CSF agent with a differentiated mechanism of action (MoA) for treating CIN. In contrast to G-CSF, Plinabulin's MoA is not associated with causing bone pain. The MoA for CIN being different between G-CSF and Plinabulin suggests that there is a strong rationale to combine these two agents together. BeyondSpring's Phase 2 data from Study 106 demonstrated statistically significant ($p < 0.05$) efficacy of Plinabulin in combination with Neulasta at 6 mg (Plinabulin/Neulasta Combo). Importantly, bone pain caused by Neulasta in more than 90% of patients was almost completely prevented by the addition of Plinabulin ($p < 0.0001$). In addition, Plinabulin attenuated the neutrophil overshoot (absolute neutrophil count over 8.0×10^9 cells/L) when added to Neulasta. Neutrophil overshoot can result in bone marrow exhaustion and immune suppression.

In Phase 2 of Study 106, patients were dosed on Neulasta on day 2, and Plinabulin on day 1, 30 minutes after TAC in the following regimens: Neulasta at 6 mg (n=21); Neulasta at 6 mg + Plinabulin (n=16); Neulasta at 3 mg + Plinabulin (n=21); and Neulasta at 1.5 mg + Plinabulin (n=14). The Plinabulin doses were 20 mg/m².

Key data from the study include the following:

Plinabulin/Neulasta Combo Demonstrated Positive Efficacy Data in Prevention of CIN

- Only 50 percent of patients treated with Plinabulin/Neulasta Combo experienced grade 3/4 CIN, versus 81 percent of patients treated with Neulasta ($p=0.0456$).
- Duration of grade 3/4 neutropenia was only 0.94 days for patients treated with Plinabulin/Neulasta Combo, versus 1.38 days for patients treated with Neulasta.

Plinabulin/Neulasta Combo Demonstrated Positive Safety Data in Prevention of CIN

- Only 6 percent of patients treated with Plinabulin/Neulasta Combo experienced at least one day of bone pain, versus 95 percent of patients treated with Neulasta ($p < 0.0001$).
 - No patients treated with the Plinabulin/Neulasta Combo experienced at least three days of bone pain, versus 38 percent of patients treated with Neulasta ($p=0.0056$).
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- Only 31 percent of patients treated with Plinabulin/Neulasta Combo experienced neutrophil overshoot, versus 52 percent of patients treated with Neulasta.

“This data suggests a potential new approach to preventing CIN and bone pain in patients receiving chemotherapy. The addition of Plinabulin to the standard TAC and Neulasta regimen appears to markedly reduce the incidence of grade 3/4 neutropenia and nearly eliminates bone pain – which are both serious limitations associated with the use of G-CSF,” said Dr. Douglas Blayne, global Principal Investigator for BeyondSpring’s CIN development program and Professor of Medicine at Stanford University. “With less neutropenia and less bone pain, more patients would be positioned to get their full dose of chemotherapy and complete their full course. This top line data suggests that the addition of Plinabulin to the standard of care for CIN therapy may meaningfully improve the current standard of care in the prevention of CIN and build upon the growing evidence for Plinabulin’s potential to change the treatment paradigm and patient outcomes in CIN.”

“We continue to build on the Plinabulin portfolio for CIN by undertaking multiple studies, involving multiple chemotherapy regimens simultaneously. Previously, we reported positive data regarding Study 105 at prominent scientific conferences (ASCO, IASLC World Conference on Lung Cancer and ESMO), demonstrating that Plinabulin has equal efficacy for CIN prevention versus Neulasta, however with a superior overall product profile (lowering of bone pain and chemotherapy-induced thrombocytopenia, and immune-suppressive potential),” added Dr. Ramon Mohanlal, EVP and Chief Medical Officer at BeyondSpring.

“Importantly, Plinabulin also exerts anticancer activity, and a large global Phase 3 trial (Study 103) is underway aimed at confirming Plinabulin’s anticancer efficacy when combined with docetaxel. Our overall development strategy for Plinabulin is to improve on the current standard of care for CIN and demonstrate anticancer efficacy by adding Plinabulin to a broad range of standard therapies for oncology. To date, Plinabulin has treated over 450 patients in clinical trials globally, with good tolerability and no cardio-safety issues. We are on track for our planned submission of a New Drug Application (NDA) for the treatment of CIN in China in late 2018 or early 2019, and in the U.S. in the second half of 2019,” concluded Dr. Mohanlal.

Conference Call and Webcast Information

The Company will host an operational update conference call on October 23, 2018 at 8:00 a.m. Eastern Time. The dial-in numbers for the conference call are (866) 362-6591 (U.S. toll free) or (706) 758-3199 (international). Please reference the conference ID number, 7880008.

A live webcast of the conference call will be available through the Investors section of BeyondSpring’s website at <http://ir.beyondspringpharma.com>. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast. A replay of the webcast will remain available on <http://ir.beyondspringpharma.com> for 30 days following the call.

About Plinabulin

Plinabulin, a marine-derived small-molecule, is BeyondSpring’s lead asset and is currently in late-stage clinical development for the prevention of chemo-induced neutropenia and as an anticancer therapy in non-small cell lung cancer. Studies of Plinabulin’s mechanism of action indicate that Plinabulin activates GEF-H1, a guanine nucleotide exchange factor. GEF-H1 activates downstream transduction pathways leading to the maturation of dendritic cells, which in turn leads to T-cell activation and the up-regulate of IL6 in the tissue micro environment, contributing to the prevention of neutropenia.

About Chemotherapy-Induced Neutropenia

Chemotherapy-induced neutropenia is a common side effect in cancer patients undergoing treatment that involves the destruction of a type of white blood cell, the neutrophil, which is a patient’s first line of defense against infections. Patients with grade 4 (severe) neutropenia have an abnormally low concentration of neutrophils, making these patients more susceptible to bacterial and fungal infections and sepsis, which can require hospitalization.

The current standard of care for chemotherapy-induced neutropenia prevention is G-CSF monotherapy. However, G-CSF monotherapy has limitations as described in its product information summary. As many as 90 percent of patients on chemotherapy and G-CSF monotherapy may still experience grade 3/4 neutropenia. NCCN guidelines require that patients with grade 3/4 neutropenia decrease chemotherapy dose intensity, delay chemotherapy cycle timing or discontinue chemotherapy, each of which can have a negative effect on the long-term outcomes of cancer care.

About BeyondSpring

BeyondSpring is a global, clinical-stage biopharmaceutical company developing innovative immuno-oncology cancer therapies with a robust pipeline from internal development and from collaboration with the University of Washington in de novo drug discovery using a ubiquitination platform. BeyondSpring's lead asset, Plinabulin, is in a Phase 3 global clinical trial as a direct anticancer agent in the treatment of non-small cell lung cancer and two Phase 2/3 clinical programs in the prevention of chemotherapy-induced neutropenia. BeyondSpring has a seasoned management team with many years of experience bringing drugs to the global market.

Cautionary Note Regarding Forward-Looking Statements

This press release includes forward-looking statements that are not historical facts. Words such as "will," "expect," "anticipate," "plan," "believe," "design," "may," "future," "estimate," "predict," "objective," "goal," or variations thereof and variations of such words and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are based on BeyondSpring's current knowledge and its present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors including, but not limited to, difficulties raising the anticipated amount needed to finance the Company's future operations on terms acceptable to the Company, if at all, unexpected results of clinical trials, delays or denial in regulatory approval process, results that do not meet our expectations regarding the potential safety, the ultimate efficacy or clinical utility of our product candidates, increased competition in the market, and other risks described in BeyondSpring's most recent Form 20-F on file with the U.S. Securities and Exchange Commission. All forward-looking statements made herein speak only as of the date of this release and BeyondSpring undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law.

Neulasta is a registered trademark of Amgen, Inc.

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BeyondSpring's Lead Asset, Plinabulin for the Prevention of Chemotherapy-Induced Neutropenia, Has the Potential to Positively Impact Tumor Microenvironment

Data Demonstrating Plinabulin's Immune-Enhancing Potential Presented at European Society for Medical Oncology (ESMO) Congress

NEW YORK – October 23, 2018 – BeyondSpring Inc. (NASDAQ: BYSI), a global, clinical-stage biopharmaceutical company focused on the development of innovative cancer therapies, presented clinical trial data on its lead asset, Plinabulin, during a poster and oral presentation at the 2018 European Society for Medical Oncology (ESMO) Congress. The data showed that, in contrast to Neulasta (pegfilgrastim), a long-acting G-CSF and the current standard of care for chemotherapy-induced neutropenia (CIN), Plinabulin did not increase the Neutrophil-to-Lymphocyte Ratio (NLR), which is a novel marker for immune suppression in the tumor microenvironment. NLR values of greater than five are a potential immunotherapy biomarker, predicting negative outcomes such as overall survival (OS) and progression-free survival (PFS) in cancer patients.

The data was derived from the Phase 2 portion of BeyondSpring's Study 105 for intermediate-risk CIN, which evaluated Plinabulin's potential to prevent CIN in patients with non-small cell lung cancer (NSCLC) following docetaxel chemotherapy. Plinabulin was administered to patients in doses up to 20 mg/m². BeyondSpring evaluated the NLR in Cycle 1 for patients receiving standard dose of docetaxel at 75 mg/m² with either Plinabulin at 20 mg/m² (n=14) or Neulasta at 6 mg (n=14). The absolute neutrophil count (ANC) was also measured.

The data presented demonstrated the following:

- **Plinabulin did not increase the NLR to immune-suppressive levels.** While treatment with Neulasta resulted in significantly increased NLR values to >5, all patients treated with Plinabulin maintained mean post-dose NLR at <5 in Cycle 1. Baseline mean NLR values were <5 in both the Plinabulin and Neulasta arms. However, the mean NLR with Neulasta increased gradually and significantly from day 7 onwards, and to a peak of 12.2 (p<0.001) on day 10. At the last timepoint measured (on day 15), the NLR with Neulasta was still significantly elevated (mean NLR of 8.11; p<0.001) versus Plinabulin.
- **With Plinabulin, ANC remained within normal range (between 2.0 and 8.0 x 10E9 cells/L) throughout the cycle.** In contrast, with Neulasta, ANC showed an overshoot to levels up to threefold (to >18 x10E9 cells/L) of the upper limit of the normal range. Lymphocyte counts were comparable for both the Plinabulin and Neulasta treatment arms.

“Along with Plinabulin's ease of use through first-day dosing, its prevention of docetaxel chemotherapy-induced-thrombocytopenia and lack of bone pain, these NLR findings further highlight what we believe to be advantages of Plinabulin compared to Neulasta,” said Douglas Blayney, global Principal Investigator for BeyondSpring's CIN development program and Professor of Medicine at Stanford University Medical Center. “The data presented at ESMO showed that Plinabulin, unlike Neulasta, did not increase NLR to potentially immune-suppressive levels. As a result, in immunotherapy settings, we believe Plinabulin could become a preferred option to prevent CIN. This data suggests that Plinabulin is an anticancer agent that offers oncologists the potential to improve treatment efficacy and reduce expensive and burdensome unplanned care – such as ER visits and hospitalizations – which are a win for both patients and physicians.”

“Immunotherapy has now established its value in the treatment of cancer, and a new trend is combining immunotherapy with chemotherapy, which typically causes CIN. Based on clinical data to date, both Neulasta and Plinabulin show equal efficacy for CIN. However, in contrast to Neulasta, this data suggests that Plinabulin does not increase NLR to immune-suppressive levels, and has immune-enhancing activity,” added Ramon Mohanlal, EVP and Chief Medical Officer of BeyondSpring.

About Study 105

The study evaluated patients with advanced or metastatic NSCLC after failing platinum-based therapy and was designed as a multicenter, open label, randomized study. In a head-to-head comparison of Plinabulin with Neulasta, a long-acting G-CSF, in a total of 55 patients, Plinabulin was shown to be comparable to Neulasta for the prevention of CIN, as assessed by the occurrence of severe (Grade 4) neutropenia and duration of severe neutropenia (DSN) in the first cycle.

Plinabulin was given as a single dose per cycle 30 minutes after docetaxel chemotherapy, while Neulasta was given 24 hours after docetaxel chemotherapy, consistent with its approved product label. The Phase 2 portion met its primary endpoint, which was to determine the recommended Phase 3 Plinabulin dose, and the Phase 3 trial is ongoing.

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