BeyondSpring's Plinabulin Continues to Build on Superior Product Profile in Breast Cancer Trial for Neutropenia Prevention

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Data to be Presented at ESMO Congress 2019 in Barcelona

NEW YORK, Sept. 23, 2019 (GLOBE NEWSWIRE) -- BeyondSpring Inc. (NASDAQ: BYSI), a global biopharmaceutical company focused on the development of innovative cancer therapies, today announced that a Company abstract with findings from BeyondSpring's Study 106 has been accepted for poster presentation at this year's European Society for Medical Oncology (ESMO) Congress in Barcelona, Spain. The poster, titled, "The Effect of Increasing Doses of Pegfilgrastim (Peg) on Thrombocytopenia (T) in Breast Cancer (BC) Patients (pts) Receiving Taxotere (Doc), Doxorubicin, Cyclophosphamide (TAC) and Plinabulin (Plin)," will be presented on Sept. 28 in Poster Hall 4.

In Study 106, BeyondSpring evaluated the effects of Pegfilgrastim (Neulasta®) combined with Plinabulin on absolute neutrophil counts and platelet count. Previously, BeyondSpring reported positive neutropenia prevention data with Pegfilgrastim combined with Plinabulin at 20mg/m^2. In this latest abstract, BeyondSpring measured the frequency of thrombocytopenia, a condition in which patients experience a low blood platelet count. The investigators analyzed thrombocytopenia in four treatment arms of breast cancer patients receiving four cycles of TAC and increasing Pegfilgrastim doses: 0 mg, or Plinabulin alone (n=15), 1.5 mg (n=14), 3 mg (n=21) or 6 mg (n=16). All patients received BeyondSpring's lead asset, Plinabulin, at 20mg/m^2. A fifth arm (n=22) received Pegfilgrastim alone at 6 mg.

BeyondSpring's data shows that the increasing Pegfilgrastim doses caused a statistically significant dose-dependent increase in thrombocytopenia ($p<0.0001$ for all grade thrombocytopenia). At the standard dose of Pegfilgrastim (6 mg), the frequency of grades 1, 2 and 3 thrombocytopenia were 56 percent, 19 percent, and 19 percent, respectively. The frequency of grades 1, 2 and 3 thrombocytopenia in the Plinabulin (20mg/m^2) treatment arm were 20 percent, 7 percent and 0 percent, which is similar to the frequency of thrombocytopenia reported with the use of TAC chemotherapy, without the use of either Pegfilgrastim or Plinabulin.

"While we know that breast cancer patients who receive chemotherapy treatment experience both neutropenia and thrombocytopenia, Pegfilgrastim itself, which is given to patients to help prevent neutropenia, seems to exacerbate chemotherapy induced thrombocytopenia," said Dr. Douglas Blayney, global Principal Investigator for BeyondSpring's Study 106 and Professor of Medicine at the Stanford University School of Medicine. "Plinabulin is highly effective for the prevention of neutropenia, without causing thrombocytopenia. Our findings add to the positive effects of Plinabulin. We previously reported that both agents are equally effective for CIN prevention, however, in contrast to Pegfilgrastim, Plinabulin does not cause bone pain or negatively impact quality of life, and here we report that it does not exacerbate thrombocytopenia."

"As a single agent, Plinabulin appears to have a superior product profile over Pegfilgrastim. When we combine Plinabulin with Pegfilgrastim, we create a superior treatment regimen that is more effective for CIN than either agent alone, while improving on the product characteristics of Pegfilgrastim alone. Not only does Plinabulin have anticancer activity, but it reduces bone pain and an immune-suppressive neutrophil profile caused by Pegfilgrastim. To date, BeyondSpring's studies have proven time and time again that Plinabulin has a differentiated mechanism of action from Pegfilgrastim, and by combining the two agents, we can combat CIN better, and provide superior supportive care than each of the agents alone," added Dr. Ramon Mohanlal, BeyondSpring's Executive Vice President, Research and Development, and Chief Medical Officer.

About BeyondSpring
BeyondSpring is a global, clinical-stage biopharmaceutical company focused on the development of innovative immuno-oncology cancer therapies. 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 (NSCLC) and two Phase 3 clinical programs in the prevention of chemotherapy-induced neutropenia (CIN). BeyondSpring has strong R&D capabilities with a robust pipeline in addition to Plinabulin, including three immuno-oncology assets and a drug discovery platform using the ubiquitination degradation pathway. The Company also has a seasoned management team with many years of experience bringing drugs to the global market.

About Plinabulin
Plinabulin, BeyondSpring's lead asset, is a marine-derived small molecule that sequesters tubulin heterodimers in a differentiated manner from other agents in this class. Plinabulin is currently in late-stage clinical development to increase overall survival in cancer patients, as well as to alleviate chemotherapy-induced neutropenia (CIN). The anticancer benefits of Plinabulin have been associated with positive effects on antigen presenting cells and T-cell activation, as well as to the direct killing of cancer cells. Plinabulin's CIN data highlights the ability to boost the number of hematopoietic stem / progenitor cells (HSPCs), or lineage-/cKit+/Sca1+ (LSK) cells in mice. Effects on HSPCs could explain the ability of Plinabulin to not only treat CIN but also to reduce chemotherapy-induced thrombocytopenia and increase circulating CD34+ cells in patients.

About Chemotherapy-Induced Neutropenia (CIN)
CIN is a common, often severe side effect that cancer patients who are undergoing treatment experience involving the destruction of neutrophils, which are a type of white blood cell and a patient's first line of defense against infections. The current standard of care for CIN prevention is G-CSF monotherapy, which has serious limitations as described in its product information summary.

As many as 90 percent of patients who receive high-risk chemotherapy and G-CSF monotherapy may still experience grade 3 or 4 neutropenia [Lee et al., Annals of Surgical treatment and research 94(5): 223-228 (2018)]. Patients with grade 4 (severe) neutropenia have an abnormally low concentration of neutrophils, making these patients more susceptible to bacterial / fungal infections and sepsis, which can require hospitalization and be fatal. Grade 4 CIN can have an adverse effect on chemotherapy administration and is usually considered a significant predictor of low relative dose intensity (RDI), dose delays and dose reductions [Lalami Y, Critical Reviews in Oncology / Hematology, 120: 163 – 179 (2017)]. Even a 15 percent chemotherapy dose reduction can reduce long-term survival by as much as 50 percent [Bonadonna, Med Oncol 29:1495–1501 (2012)].

Additionally, as many as 70 percent of patients using G-CSF monotherapy experience bone pain [Moore et al., Annals of Pharmacotherapy 51(9): 797-803 (2017)]. Twenty-five percent of patients also report that the pain is severe. The National Comprehensive Cancer Network (NCCN) guidelines require that patients with grade 3 or 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 [Lalami et al., Critical Reviews in Oncology / Hematology 120: 163-179 (2017)].

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.

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