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BeyondSpring Enrolls First Patient in Global Phase 3 Clinical Trial with Plinabulin in combination with G-CSF to Prevent Chemotherapy-Induced Neutropenia

NEW YORK, Oct. 23, 2019 (GLOBE NEWSWIRE) -- BeyondSpring Inc. (NASDAQ: BYSI), a global biopharmaceutical company focused on the development of innovative immuno-oncology cancer therapies, today announced that the Company has enrolled its first patient in a Phase 3, Study 106, clinical trial with its lead asset, Plinabulin, for the prevention of chemotherapy-induced neutropenia (CIN). Study 106 is enrolling patients receiving TAC (taxotere, doxorubicin and cyclophosphamide) chemotherapy plus Neulasta vs. TAC plus Plinabulin and Neulasta, to demonstrate Plinabulin's exceptional ability to prevent CIN. The principal investigator of the study is Dr. Douglas Blayney, Professor of Medicine from Stanford University.

"The first patient enrolled in our Phase 3 Study 106 is an important step as we move closer to bringing Plinabulin to market for CIN, which is a serious health concern and causes decreases in dose, delay of chemotherapy cycles and downgrade – or even discontinue – treatment altogether, which affects chemotherapy's anti-cancer benefit," said Dr. Ramon Mohanlal, BeyondSpring's EVP of R&D and Chief Medical Officer. "Many publications show a 15% reduction in relative dose intensity (RDI) can result in a 50% reduction in long term survival. Currently for TAC treatment (Study 106 design), even with the use of G-CSF monotherapy, over 90% of patients still had grade 3 and 4 neutropenia in the first cycle, which potentially puts patients at a significant risk of adverse changes in later cycles. Patients treated with the Plinabulin plus G-CSF combo in phase 2 had only 50% grade 3 and 4 neutropenia, >30% reduction compared to monotherapy G-CSF. The phase 3 study is the key platform to confirm this finding and bring improved care to patients."

"Given its novel mechanism of action, Plinabulin holds the promise of being a groundbreaking therapy for cancer patients with its unique ability to prevent CIN and acts as an anti-cancer drug with immune-enhancing effects," said Dr. Lan Huang, CEO and co-Founder of BeyondSpring. "The regulatory agencies have been very supportive of our CIN and NSCLC clinical programs to support both proposed indications and we anticipate NDA filings for both indications with China's National Medical Products Administration (NMPA) in the first quarter of 2020, and with the U.S. Food and Drug Administration (FDA) in 2020."

Neutropenia is a common side effect of chemotherapy in cancer patients, which marks the destruction of a type of white blood cell (neutrophil) that is a key component of the innate immune system. Neutrophils are a patient's first line of defense against infections, and patients with severe neutropenia are more susceptible to bacterial, viral and fungal infections in addition to sepsis, which require hospitalization and has a high mortality risk. Around 1 million people in the US receive chemotherapy each year. With the approval of chemotherapy with checkpoint inhibitors, chemotherapy remains a cornerstone of cancer treatment, and increase 50% from now to 2040 based on a May 2019 Lancet article (1).

Reference:
1. Wilson BE et al. Estimate of global chemotherapy demands and corresponding physician workforce requirements for 2018 and 2040: a population-based study. Lancet 20(6): P769-780 (2019)

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 positively affect 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.

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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