BeyondSpring Pharmaceuticals Enrolls First U.S. Patient In Phase II/III Clinical Trial Of Plinabulin For Neutropenia Prevention

BeyondSpring Inc. (NASDAQ:BYSI), a global clinical stage biopharmaceutical company focused on the development of innovative cancer therapies, today announced that the Company has enrolled the first patient at the Hematology / Oncology Northshore, Illinois, in its Phase 2/3 study of BeyondSpring's lead asset, Plinabulin, for the prevention of neutropenia, in combination with docetaxel.

"We have reached our first milestone with enrollment of the first U.S. patient in BeyondSpring's trial for the prevention of neutropenia – a serious health issue that cancer patients throughout the world deal with daily," said Douglas Blayney, M.D., FACP, Professor of Medicine (Oncology) at Stanford University and Principal Investigator for BeyondSpring's neutropenia registrational trial. "We are eager to push Plinabulin forward for the prevention of chemotherapy-induced neutropenia, as this is an area with a continuing unmet need, where no new treatments have been introduced in the last 25 years. Plinabulin has the potential to improve both the care and quality of life for cancer patients who are receiving chemotherapy worldwide."

Plinabulin has produced encouraging data regarding the reduction of severe neutropenia, a common and potentially life-threatening adverse effect of chemotherapy. Plinabulin can be administered one hour after chemotherapy and has the potential to be an attractive alternative to G-CSF, the current standard of care for chemotherapy-induced neutropenia.

Plinabulin would offer a same-day dosing advantage over G-CSF, which is typically administered 24 hours after chemotherapy, per G-CSF label (next-day dosing), by which time significant damage to the neutrophils can occur. Additionally, Plinabulin has demonstrated, in the Phase 2 portion of a Phase 1/2 trial in combination with docetaxel in patients with advanced non-small cell lung cancer, a reduction in clinical sequelae associated with docetaxel-induced neutropenia, including infections, sepsis, hospitalizations and the need for docetaxel dose reductions.

"BeyondSpring is looking forward to the results of the trial of Plinabulin for chemotherapy-induced neutropenia," added Dr. Lan Huang, Ph.D., BeyondSpring CEO. "Our team is committed to revolutionizing cancer care and providing innovative treatments for patients with high unmet medical needs. Starting U.S. patient enrollment brings us one step closer to bringing Plinabulin to market."

Neutropenia, a common side effect of chemotherapy in cancer patients, is 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 (grade 4) neutropenia (an abnormally low concentration of neutrophils in the blood) are more susceptible to severe bacterial, viral and fungal infections and sepsis, which require hospitalization.

More than 60,000 patients in the U.S. are hospitalized each year for chemotherapy-induced severe neutropenia, which is associated with fever and infections, leading to death in up to 18 percent of these cases. When severe neutropenia occurs, the chemotherapy dose may be reduced or interrupted until neutropenia subsides. This reduction or interruption results in suboptimal chemotherapy cancer treatment in a patient.

"Being a potentially potent neutropenia-preventing drug, with anti-cancer activity, would be an important differentiating feature of Plinabulin, if approved, over G-CSF and its analogues," concluded Dr. Ramon Mohanlal, M.D., Ph.D., BeyondSpring Chief Medical Officer, who also leads the partnering efforts at

BeyondSpring. “This may enable Plinabulin to be more preventive than G-CSF for severe neutropenia, because Plinabulin can be administered one day earlier than G-CSF and its analogues. We continue our search for strong partners to join us in transforming the potential of Plinabulin to commercial fruition.”

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 Fred Hutchinson Cancer Research Center and University of Washington. BeyondSpring’s lead asset, Plinabulin, is in a Phase 3 clinical trial as a direct anticancer agent in non-small cell lung cancer and a Phase 2/3 clinical trial in the prevention of chemotherapy-induced neutropenia. BeyondSpring has a seasoned management team with many years of experience bringing drugs to market.

About Plinabulin
Studies on Plinabulin's method of action indicate that Plinabulin activates GEF-H1, a guanine nucleotide exchange factor. GEF-H1 activates downstream transduction pathways leading to the activation of the protein c-Jun. Activated c-Jun enters the nucleus of dendritic cells to upregulate immune-related genes, which contributes to the up-regulation of a series of genes leading to dendritic cell maturation, T-cell activation and other effects that prevent neutropenia.

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, the anticipated amount needed to finance the company's future operations, unexpected results of clinical trials, delays or denial in regulatory approval process, our expectations regarding the potential safety, efficacy or clinical utility of our product candidates, or additional competition in the market. The 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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