BeyondSpring Presents Novel Trial Design for DUBLIN-3 Study BPI-2358-103 at ESMO Congress 2019

October 1, 2019

DUBLIN-3 Designed to Overcome Challenges Associated with Trial Failure Risk, According to New Data in Non-Small Cell Lung Cancer Studies

NEW YORK, Oct. 01, 2019 (GLOBE NEWSWIRE) -- BeyondSpring Inc. (NASDAQ: BYSI), a global biopharmaceutical company focused on the development of innovative immune-oncology cancer therapies, today announced that the Company's novel trial design for DUBLIN-3 (Study BPI-2358-103) for its lead asset and first-in-class agent, Plinabulin, was selected for poster presentation at this year's European Society for Medical Oncology (ESMO) Congress in Barcelona, Spain. The poster, titled, "DUBLIN-3, a Stage IIIb/IV NSCLC Phase (Ph)3 Trial Comparing the Plinabulin (P)/Docetaxel(D) Combination with D Alone," was presented on September 28.

The PD-L1 inhibitors Avelumab and Atezolizumab have demonstrated proven clinical anticancer efficacy. In second- and third-line non-small cell lung cancer (NSCLC) trials, however, Avelumab (Javelin Lung 200) failed, whereas Atezolizumab (OAK) met its primary endpoint and showed better overall survival versus Docetaxel as a comparator at 75 mg/m^2. The Javelin authors pointed out that study design considerations may have led to the negative trial outcome, such as its open-label design (which led to more Docetaxel patients dropping out prior to receiving their first dose) and lack of stratification for region (Asian patients tend to respond better to Docetaxel than non-Asians). In addition, relatively low immunogenicity associated with later-stage tumors in patients may have played a role in the negative outcome of the trial.

In contrast, BeyondSpring's global Phase 3 DUBLIN-3 trial, Study 103 is a single-blinded study in EGFR wild-type, stage IIIb/IV NSCLC patients (n=554) stratified for region (Asia / non-Asia) and receiving second- or third-line therapy with the Docetaxel-Plinabulin combination or Docetaxel alone in a 1:1 ratio. Patients with at least one measurable lung lesion (per RECIST 1.1 criteria) were included. Patients should have failed a prior platinum-based regimen and patients who had failed prior PD-1 / PD-L1 immunotherapy could enter the study. Overall survival is the primary endpoint.

Both Javelin and DUBLIN-3 have Docetaxel 75 mg/m^2 as the comparator arm. In comparison to Avelumab, Phase 2 data with the Plinabulin-Docetaxel combination demonstrated better overall survival for patients, plus a better safety profile and quality of life (QoL) compared to Docetaxel monotherapy. Additionally, patients receiving Plinabulin experienced the safety benefit of less severe neutropenia. DUBLIN-3 is designed to build on the lessons learned through the design pitfalls of Javelin, as pointed out by its authors, as it pertains to:

- Blinding to patients
- Stratification for region
- Inclusion of patients with tumors with a higher probability of still being immunogenic, such as measurable lung lesions with presence in the lung

"When going up against Docetaxel – an established, highly effective treatment for second- and third-line NSCLC – for a comparison trial, Avelumab may have failed due to critical trial design considerations, which were avoided with the design of DUBLIN-3," said Dr. Ramon Mohanlal, BeyondSpring's Executive Vice President, R&D, and Chief Medical Officer. "With PD-1 inhibitor therapy (in combination with platinum/pemetrexed) moving into first-line NSCLC, PD-1/PD-L1 inhibitors are no longer an option in second- and third-line for patients who became resistant to them in first-line treatment. Therefore, Docetaxel is the standard of care for second- and third-line NSCLC. If the Plinabulin/Docetaxel combination meets its intended target product profile of superior survival benefit, superior safety and QoL compared to Docetaxel alone, it has the potential to become the preferred second- and third-line treatment option in NSCLC. Based on the first pre-planned interim analysis with DUBLIN-3 in Q1 2019, the study could continue without modifications, as concluded by the DSMB. The second interim analysis is projected for Q1 2020, after which the trial could be stopped, if pre-specified statistics are met."

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.

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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