

BeyondSpring Announces Positive Topline Interim Results from PROTECTIVE-2 (Study 106) Phase 3 Trial Evaluating Superiority of Plinabulin in Combination with Neulasta for Chemotherapy-Induced Neutropenia Prevention

-Met Primary Endpoint of Rate of Severe (Grade 4) Neutropenia Prevention in First Chemotherapy Cycle (Cycle 1) ($p < 0.01$)-

-Met Key Secondary Endpoint of Duration of Severe Neutropenia (DSN) of Cycle 1 ($p < 0.05$)-

-Met Key Secondary Endpoint of DSN in First Eight Days of Cycle 1 ($p < 0.05$), Supporting Plinabulin's Early Onset Action-

-Results Support Superior Profile of Plinabulin-Neulasta Combination Versus Neulasta Alone-

-Potential for First Superior Therapy and Significant Enhancement to G-CSFs in Preventing Neutropenia in Last 30 Years-

-Conference Call and Webcast Will Be Held Today at 8:30 a.m. ET-

NEW YORK – June 15, 2020 – BeyondSpring (the “Company” or “BeyondSpring”) (NASDAQ: BYSI), a global biopharmaceutical company focused on the development of innovative immuno-oncology cancer therapies, today announced positive topline results at the pre-specified interim analysis of its PROTECTIVE-2 (Study 106) Phase 3 trial, evaluating Plinabulin in combination with Neulasta versus Neulasta alone. Neulasta is a long-lasting G-CSF that is the current standard of care for treating chemotherapy-induced neutropenia (CIN). The interim results have shown significant enhancement of the combination over Neulasta in the rate of Grade 4 neutropenia prevention ($p < 0.01$), the primary endpoint for the study.

The PROTECTIVE-2 Phase 3 study is a double-blind, active controlled, global trial, with the pre-specified interim analysis at approximately 120 patients accrued. The interim results also met its key secondary endpoint, the duration of severe neutropenia (DSN) in Cycle 1 ($p < 0.05$). The DSN in Cycle 1, the original primary endpoint prior to a protocol amendment, is the current standard for CIN study regulatory approval. In addition, another key secondary endpoint, DSN in the first eight days of Cycle 1, was also met ($p < 0.05$), supporting Plinabulin's mechanism of action in providing early protection against severe neutropenia, as Neulasta alone is known to protect against severe neutropenia typically from Day 9 onward. Therefore, the complementary mechanism would potentially give full protection in Cycle 1.

Procedures are in place to prevent potential bias after the planned interim analysis. The Company opted to be informed by independent statisticians only whether the pre-specified p-values were met, instead of the exact p-values.

“We are extremely excited about the topline results from the interim analysis of PROTECTIVE-2 Phase 3. With these breakthrough data, coupled with the consistent data generated across our six independent clinical trials on over 1,200 patients, we aim to cover new ground in developing a treatment that prevents severe neutropenia, instead of just merely reducing it, as with the current standard of care,” said Dr. Lan Huang, BeyondSpring's CEO and Co-Founder.

“These interim results from the PROTECTIVE-2 Phase 3 study, which compares the Plinabulin-Neulasta combination to Neulasta alone, have the potential to be clinically meaningful for cancer patients receiving chemotherapy,” said Dr. Douglas Blayney, Professor of Medicine at Stanford Medical School and global Principal Investigator of Plinabulin's CIN studies. “Since most infections, hospitalizations and other complications of CIN occur in the first week after chemotherapy, it is particularly gratifying to see the combination's clinical benefit demonstrated. These results could help to confirm the patient benefit of

Plinabulin's different mechanism of action from the G-CSF-based agents, such as Neulasta. Plinabulin appears to have CIN protection in Week 1, and G-CSFs have protection in Week 2 of chemotherapy cycles. The combination should logically provide significantly better protection than Neulasta alone as shown in the interim readout. We are well on our way to confirming that the combination offers protection throughout the chemotherapy cycle, which is an unmet medical need."

“This interim result shows Plinabulin-Neulasta combination’s potential for the first superior therapy and significant enhancement to G-CSF in preventing neutropenia in the last 30 years,” concluded Dr. Huang. “Today’s announcement marks the results of years of hard work and a significant step in fulfilling our mission. In the COVID-19 pandemic, the ability to reduce severe neutropenia, which is directly linked to both infections and hospitalizations, has become increasingly important for immune-compromised cancer patients. We have a unique opportunity to potentially bring this innovative therapy to the patients with unmet medical needs.”

Conference Call and Webcast Information

BeyondSpring’s management will host a conference call and webcast today at 8:30 a.m. Eastern Time. The dial-in numbers for the conference call are 1-877-451-6152 (U.S.) or 1-201-389-0879 (international). Please reference conference ID: 13705449. A live webcast will be available on BeyondSpring’s website at www.beyondspringpharma.com under “Events & Presentations” in the Investors section. An archived replay of the webcast will be available for 30 days.

About BeyondSpring

BeyondSpring is a global, clinical-stage biopharmaceutical company focused on the development of innovative immuno-oncology cancer therapies. BeyondSpring’s lead asset, first-in-class agent Plinabulin as an immune and stem cell modulator, 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 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 protein degradation pathway. The Company also has a seasoned management team with many years of experience bringing drugs to the global market. BeyondSpring is headquartered in New York City.

About Plinabulin

Plinabulin, BeyondSpring’s lead asset, is a differentiated immune and stem cell modulator. Plinabulin is currently in late-stage clinical development to increase overall survival in cancer patients, as well as to alleviate CIN. The durable anticancer benefits of Plinabulin have been associated with its effect as a potent antigen-presenting cell (APC) inducer (through dendritic cell maturation) and T-cell activation (*Chem and Cell Reports*, 2019). 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 with a rapid onset, but also to reduce chemotherapy-induced thrombocytopenia and increase circulating CD34+ cells in patients.

About Plinabulin in PROTECTIVE-2 (Study 106) CIN Study

The Phase 3 portion of PROTECTIVE-2 is a double-blind and active controlled global study. It was designed to evaluate the safety and efficacy in breast cancer, treated with docetaxel, doxorubicin and cyclophosphamide (TAC, Day 1 dose) in a 21-day cycle with Plinabulin (40mg, Day 1 dose) + Neulasta (6mg, Day 2 dose) versus a single dose of Neulasta (6mg, Day 2 dose). TAC is an example of high-risk chemotherapy. Plinabulin and G-CSF have complementary mechanisms in preventing chemotherapy-induced neutropenia (CIN). This is a superiority study in CIN efficacy in the rate of prevention of Grade 4 neutropenia, comparing the combination head-to-head against Neulasta, and is currently enrolling. Literature shows that the Grade 4 neutropenia rate for TAC and Neulasta at 6mg is 83 to 93 percent, which presents severe unmet medical needs.

The absolute neutrophil count (ANC) data, which is used to calculate these endpoints, was obtained through central laboratory assessments by Covance Bioanalytical Methods using standardized and validated analytical tests. Covance was the clinical contract research organization (CRO) for patient recruitment and monitoring of global sites for this study.

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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