



CONFIDENTIAL DRAFT

BeyondSpring Pharmaceuticals Receives Complete Response Letter from the FDA for Plinabulin New Drug Application for Prevention of Chemotherapy-Induced Neutropenia (CIN)

NEW YORK, December 1, 2021 — BeyondSpring Pharmaceuticals (the “Company” or “BeyondSpring”) (NASDAQ: BYSI), a global pharmaceutical company focused on the development of cancer therapeutics, today announced it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) seeking approval of plinabulin in combination with granulocyte colony-stimulating factor (G-CSF) for the prevention of chemotherapy-induced neutropenia (CIN). The FDA issued the CRL to indicate that they have completed their review of the application and have determined that it cannot be approved in its present form.

The FDA’s CRL indicated that the results of the single registrational trial (106 Phase 3) was not sufficiently robust to demonstrate benefit and that a second well controlled trial would be required to satisfy the substantial evidence requirement to support the CIN indication.

“BeyondSpring strongly believes that plinabulin in combination with G-CSF has significant potential to raise the standard of care in CIN, a devastating side effect of chemotherapy,” said Dr. Lan Huang, BeyondSpring’s co-founder, chief executive officer and chairwoman. “The Company plans to request a meeting with the FDA and remains committed to its goal of bringing plinabulin to cancer patients in need globally.”

BeyondSpring remains confident in the efficacy and safety data for plinabulin in combination with G-CSF for the prevention of CIN. The Company expects to work closely with the FDA to consider the possible future clinical pathway for CIN, which may include a second study.

Plinabulin is the first drug candidate submitted for FDA approval that has the potential to work in the critical first week of chemotherapy treatment before G-CSF is effective, to prevent the onset and improve clinical outcomes of CIN.

About Plinabulin

Plinabulin, BeyondSpring’s lead asset, is a selective immunomodulating microtubule-binding agent (SIMBA), which is a potent antigen presenting cell (APC) inducer. It is a novel, intravenous infused, patent-protected, NDA-stage asset for CIN prevention and a Phase 3 anti-cancer candidate for non-small cell lung cancer (NSCLC) with recently released positive topline data. Plinabulin triggers the release of the immune defense protein, GEF-H1, which leads to two distinct effects: first is a durable anticancer benefit due to the maturation of dendritic cells resulting in the activation of tumor antigen-specific T-cells to target cancer cells, and the second is early-onset of action in CIN prevention after chemotherapy by boosting the number of hematopoietic stem/progenitor cells (HSPCs). Plinabulin received Breakthrough Therapy designation and priority review from both U.S. and China FDA for the CIN prevention indication. As a “pipeline in a drug,” plinabulin is being broadly studied in combination with various immuno-oncology agents that could boost the effects of the PD-1/PD-L1 antibodies and re-sensitize PD-1/PD-L1 antibody-resistant patients.



About BeyondSpring Pharmaceuticals

Headquartered in New York City, BeyondSpring is a global biopharmaceutical company focused on developing innovative cancer therapies to improve clinical outcomes for patients who have high unmet medical needs. BeyondSpring's first-in-class lead asset, plinabulin, is being developed as a "pipeline in a drug" in various cancer indications as a direct anti-cancer agent and to prevent chemotherapy-induced neutropenia (CIN). The plinabulin and G-CSF combination for the prevention of CIN has demonstrated positive Phase 3 data. In the DUBLIN-3 study, a global, randomized, active controlled Phase 3 study, the plinabulin and docetaxel combination has met the primary endpoint of extending overall survival compared to docetaxel alone, in 2nd/3rd line NSCLC (EGFR wild type). Additionally, plinabulin is being broadly studied in combination with various immuno-oncology regimens that could boost the efficacy of PD-1/PD-L1 antibodies in seven different cancers. In addition to plinabulin, BeyondSpring's pipeline includes three pre-clinical immuno-oncology assets and a subsidiary, SEED Therapeutics, which is leveraging a proprietary targeted protein degradation drug discovery platform.

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 the Company's expectations regarding the potential safety, the ultimate efficacy or clinical utility of its 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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