Exhibit 99.1

BeyondSpring Announces Submission of New Drug Application to U.S. FDA and China NMPA for Plinabulin and G-CSF Combination for the Prevention of Chemotherapy-Induced Neutropenia (CIN)

- *Applications are supported by positive PROTECTIVE-2 Phase 3 data demonstrating that plinabulin in combination with G-CSF offers greater protection against CIN than the standard of care, G-CSF alone*

- *Plinabulin's MoA is distinct from, yet complementary to that of G-CSF, acting in Week 1 of the chemotherapy cycle, where over 75% of CIN-related complications occur, with G-CSF acting in Week 2*

NEW YORK, March 31, 2021 (GLOBE NEWSWIRE) -- BeyondSpring Inc. (the "Company" or "BeyondSpring") (NASDAQ: BYSI), a global biopharmaceutical company focused on the development of innovative cancer therapies, today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and the China National Medical Products Administration (NMPA) for use of plinabulin in combination with granulocyte colony-stimulating factor (G-CSF) for the prevention of chemotherapy-induced neutropenia (CIN). Plinabulin in combination with a G-CSF therapy, which received breakthrough therapy designation from the U.S. FDA and the China NMPA for "concurrent administration with myelosuppressive chemotherapeutic regimens in patients with non-myeloid malignancies for the prevention of CIN," has the potential to raise the standard of care in CIN for the first time in 30 years.

CIN remains a severely unmet medical need. Treatment or prevention of CIN with G-CSF has been the standard of care since Neupogen® was approved in 1991. The main benefit of G-CSF treatment, however, is in Week 2 after chemotherapy. Week 1 after chemotherapy is considered the "neutropenia vulnerability gap" where over 75% of CIN-related clinical complications occur, including febrile neutropenia, infection, hospitalization and death. Plinabulin is the first agent seeking FDA approval that has the potential to fill this gap by working in Week 1 to prevent the onset and progression of CIN. Therefore, combining plinabulin and G-CSF may maximize the protection of patients for the full cycle of chemotherapy, as demonstrated in the PROTECTIVE-2 Phase 3 registration study.

"CIN is a major concern for physicians and their patients undergoing cancer treatment. Plinabulin provides benefits above and beyond what is currently available on the market and has the potential to be a game-changer for patients undergoing chemotherapy treatment," said Dr. Douglas Blayney, Professor of Medicine at Stanford University Medical School and global PI for CIN studies. "CIN, which can lead to life-threatening infections, is the number one reason for the 4D's in chemotherapy (Decrease, Delay and Discontinue dose and Downgrade regimen). We hope plinabulin will allow patients to better tolerate chemotherapy, thus enabling patients to stick to their optimal treatment plan and avoid serious CIN complications."

The NDA submission is based on positive data from BeyondSpring's PROTECTIVE-2 Phase 3 registration study which showed that plinabulin in combination with pegfilgrastim demonstrated superior CIN prevention benefit, compared to pegfilgrastim alone. The study met the primary endpoint, with a statistically significant improvement in the rate of prevention of grade 4 neutropenia (improved from 13.6% to 31.5%, p=0.0015) and met all key secondary endpoints, including duration of severe neutropenia (DSN) and absolute neutrophil count (ANC) nadir. In addition, the combination reduced clinical complications such as incidence and severity of febrile neutropenia (FN) and incidence and duration of hospitalization for FN patients. The combination is well tolerated, with an over 20% reduction of grade 4 Treatment-Emergent Adverse Events (TEAE) in the combination compared to that of pegfilgrastim alone. The NDA submissions will include five supportive trials that show consistent CIN prevention in various chemotherapy regimens and cancers in over 1,200 patients.

"This NDA submission is the culmination of years of research to prove that plinabulin can improve the long-established standard of care and address an unmet medical need to further alleviate the risk burden of CIN for patients receiving chemotherapy," said Dr. Lan Huang, co-founder, CEO, and chairman of BeyondSpring. "With CIN responsible for potentially delaying treatment and causing life-threatening infections, we hope that receiving the improved care represented by the plinabulin and G-CSF combination will allow patients to better tolerate chemotherapy and potentially see increased treatment success rates. We are grateful for the patients' participation in plinabulin's clinical trials and the participation and contributions of our investigators and our many other clinical partners."

Each year in the U.S., 110,000 patients receiving chemotherapy are hospitalized after developing CIN, a severe side effect that increases the risk of infection with fever (also called febrile neutropenia, or "FN"), which necessitates ER/hospital visits. Due to the COVID-19 pandemic, the updated National Comprehensive Cancer Network (NCCN) guidelines expanded the use of prophylactic G-CSFs, including pegfilgrastim, from high-risk patients only (chemo FN rate >20%), to include intermediate-risk patients (FN rate between 10-20%), to reduce the number of hospital/ER visits related to CIN. The revision of the NCCN guidelines effectively increases the addressable market of patients who may benefit from treatment with plinabulin, if approved, to approximately 440,000 cancer patients in the U.S. annually.

There is a large unmet medical need and a growing market for CIN prevention and treatment in China as well. According to *Lancet Oncology*, 60% of East Asia cancer patients are treated with chemotherapy1. In 2020, there were 4.6 million new cancer patients in China which could correspond to 2.8 million patients using chemotherapy and needing CIN prevention agents. According to IQVIA data, the G-CSF drug market (for CIN treatment) in China is growing at over 30% a year.

About PROTECTIVE-2 (Study 106) Phase 3 Registration Study
The Phase 3 portion of PROTECTIVE-2 was a double-blind and active-controlled global registration study. It was designed as a superiority study to compare the safety and efficacy of plinabulin (40 mg, Day 1 dose) + pegfilgrastim (6 mg, Day 2 dose) versus a single dose of pegfilgrastim (6 mg, Day 2 dose) in patients with breast cancer, treated with docetaxel, doxorubicin and cyclophosphamide (TAC, Day 1 dose) in a 21-day cycle. TAC is an example of high FN risk chemotherapy and is the regimen used in all G-CSF biosimilar registration studies.

The primary endpoint was the rate of prevention of Grade 4 neutropenia and secondary endpoints included DSN and mean ANC nadir in Cycle 1. Literature shows that despite the use of pegfilgrastim, 83 to 93 percent of patients treated with TAC still suffer Grade 4 neutropenia (or rate of Grade 4 neutropenia prevention at 7-17%), which demonstrates the severe unmet medical need for improved treatment2,3.

The ANC data, which are used to calculate these endpoints, were 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.

About CIN
Chemotherapy-induced neutropenia (CIN) is the primary dose-limiting toxicity in cancer patients who receive chemotherapy and is the primary cause for the 4D's (Decrease, Delay, Discontinue dose and Downgrade regimen). The 4D's lead to a decrease of the anti-cancer benefit of chemotherapy, e.g., >15% of dose reduction correlated to >50% survival reduction4. The National Comprehensive Cancer Network (NCCN) recently updated its treatment guidelines for CIN prophylaxis using G-CSFs to include both high- and intermediate-FN risk patients treated with chemotherapies, to preserve hospital and ER resources for COVID-19 patients, and to maximize protection from CIN. The NCCN's action effectively doubled the number of patients recommended to receive CIN prophylaxis.

About Plinabulin
Plinabulin, BeyondSpring's lead asset, is a selective immune-modulating microtubule-binding agent (SIMBA). A global Phase 3 clinical trial in CIN (PROTECTIVE-2) with plinabulin in combination with pegfilgrastim versus pegfilgrastim alone has been completed and is the basis for an NDA filing in the U.S. and China for the prevention of CIN. In this trial, plinabulin reduced the "neutropenia vulnerability gap" associated with G-CSF therapy alone. Additionally, a global Phase 3 study for the treatment of later-stage NSCLC in EGFR wild-type patients (DUBLIN-3) is now fully enrolled and will evaluate the combination of plinabulin and docetaxel versus docetaxel alone for overall survival in NSCLC patients. 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 cells5,6 and the second is early-onset action in CIN prevention after chemotherapy by boosting the number of hematopoietic stem/progenitor cells (HSPCs)7. Effects on HSPCs could explain the potential for plinabulin not only to prevent CIN but also to increase circulating CD34+ cells in patients. 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.

About BeyondSpring
Headquartered in New York City, BeyondSpring is a global biopharmaceutical company focused on developing innovative immuno-oncology cancer therapies to improve clinical outcomes for patients who have high unmet medical needs. BeyondSpring's first-in-class lead asset plinabulin is a "pipeline in a drug." It is filed for approval in the US and China for the prevention of chemotherapy-induced neutropenia (CIN) and has a fully enrolled pivotal study to test an anti-cancer benefit with an overall survival primary endpoint in non-small cell lung cancer (NSCLC). Additionally, it is being broadly studied in combination with various immuno-oncology agents that could boost the effects of PD-1 / PD-L1 antibodies. In addition to plinabulin, BeyondSpring's extensive pipeline includes three pre-clinical immuno-oncology assets and a subsidiary, SEED Therapeutics, which is leveraging a proprietary targeted protein degradation drug discovery platform.

References:

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