BACKGROUND
Plinabulin, is a first-in-class, selective immunomodulating microtubule-binding agent (SIMBA)
• Chemotherapy-induced neutropenia (CIN) protection
• Reduces febrile neutropenia, hospitalizations and other complications of myelosuppressive chemotherapy
• Plinabulin also has anti-cancer activity

METHODS
PROTECTIVE-2 (NCT03294577) is a global, multicenter, randomized, double-blind study to evaluate severe neutropenia in early-stage breast cancer patients.

RESULTS

Abstract #533: Clinical Trial Testing Superiority of Combination Plinabulin and Pegfilgrastim vs Pegfilgrastim Alone in Patients with Breast Cancer Treated with High Febrile Neutropenia Risk Chemotherapy: Final Results of the Phase 3 Chemotherapy-Induced Neutropenia Prevention Trial (PROTECTIVE-2)

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Combination Plinabulin/Pegfilgrastim
VS.

Pegfilgrastim alone

• Superior CIN protection

Higher ANC count (~100% higher) in the combination is correlated with ~50% reduction in the incidence and severity of FN, and its related hospitalization, and chemo dose reduction/change in later cycles

• No added toxicity

• Reduced severity of treatment related adverse events

>20% reduction in Grade 4 TEAE

Bone pain AE frequency 18.0% (combination) vs 30.0% (pegfilgrastim), p=0.03

FUTURE DIRECTIONS FOR RESEARCH
Explore
• Plinabulin activity in other solid tumors and other chemotherapy
• Hematologic malignancy
• Synergy with I/O agents and radiation therapy
• Ongoing Pediatric sarcoma study

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BACKGROUND

Combination Plinabulin/Pegfilgrastim

N= 111

Day 1: TAC chemotherapy, Plinabulin 40 mg
Day 2: Pegfilgrastim 6 mg

N= 110

Day 1: TAC chemotherapy, Pegfilgrastim 6 mg
Day 2: Pegfilgrastim 6 mg

Primary endpoint (tested for superiority):
• Percentage of patients who had no days of severe neutropenia (DSN) in Cycle 1.

Secondary endpoints:
• Meanabsolute neutrophil count (ANC) nadir in Cycle 1.
• Access Incidence of Febrile Neutropenia (NCCN Definition).
• To compare proportion of patients who needed bone pain medication.

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