

Abstract #547: Head-to-Head Comparison of Single Agent Plinabulin versus Pegfilgrastim for the Prevention of Chemotherapy-Induced Neutropenia in the Phase 3 Clinical Trial- PROTECTIVE-1

Authors: Douglas Blayney MD FASCO, Yuankai Shi MD PhD, Igor Bondarenko MD PhD, Stephan Ongenstad PhD, Qingyuan Zhang MD, Lihua Du, Lan Huang PhD, Ramon Mohanlal MD PhD.

BACKGROUND

Plinabulin, is a first-in-class, selective immunomodulating microtubule-binding agent (SIMBA)

- NOT a G-CSF.
- Chemotherapy-induced neutropenia (CIN) protection.
- Reduces febrile neutropenia, hospitalizations and other complications of myelosuppressive chemotherapy.
- In contrast to pegfilgrastim, plinabulin does not cause bone pain or thrombocytopenia, and maintains quality of life.
- Plinabulin also has anti-cancer activity.

STUDY DESIGN

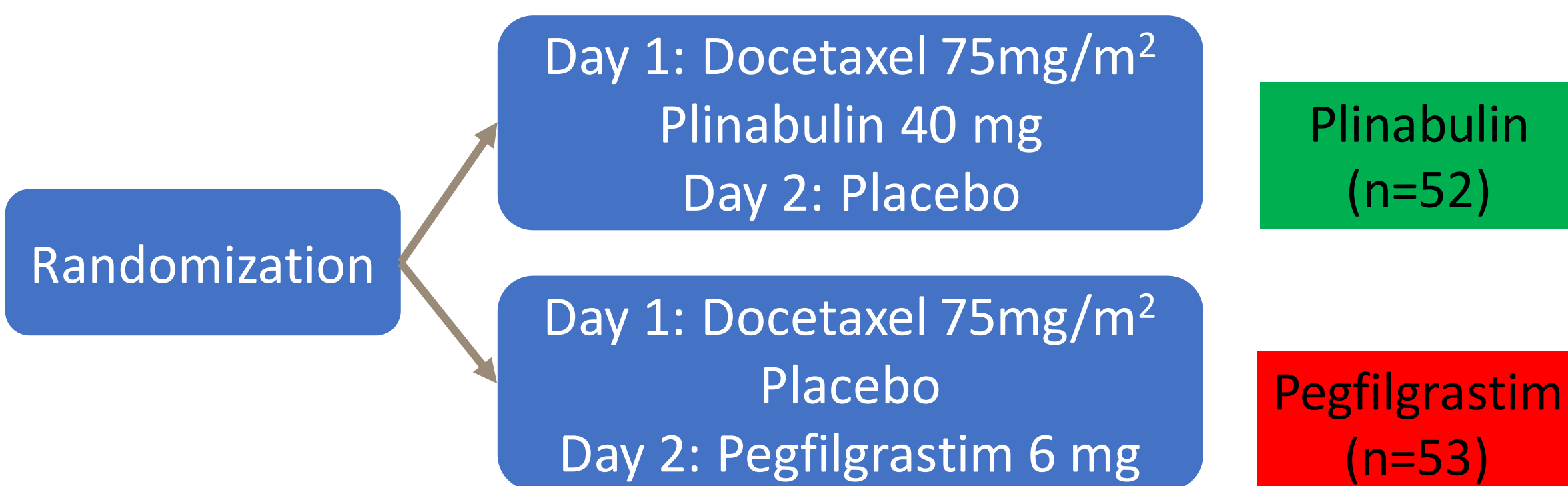
PROTECTIVE-1(NCT03102606) – A global, multicenter, randomized, double-blind study to evaluate prevention of CIN in NCCN intermediate risk chemotherapy (docetaxel) in breast cancer, NSCLC and HRPC with at least 1 risk factor. 4 cycles.

PRIMARY OBJECTIVE:

- To demonstrate Non-Inferiority of single agent plinabulin vs single agent pegfilgrastim for duration of severe neutropenia (DSN) in Cycle 1.

EXPLORATORY OBJECTIVES:

- To explore the clinical sequelae of CIN and bone pain scores.



Single Agent Plinabulin

VS

Standard of Care Pegfilgrastim for CIN Prevention

- Was Non-Inferior for CIN prevention
- **Showed reduced in CIN clinical sequelae for Febrile neutropenia, Infection, Antibiotic use, Hospitalization rate, Docetaxel discontinuation and Docetaxel delays**
- **Significant improvement in bone pain & platelet count**
 - Same day convenience of use
 - Comparable safety profile
 - Anticancer activity



Corresponding Authors:

Douglas W. Blayney, MD - DBlayney@Stanford.edu
 Ramon Mohanlal, MD, PhD - rmohanlal@beyondspringpharma.com

RESULTS

Primary endpoint was met using a Non-Inferiority Margin of 0.65 Day

- The mean DSN difference between plinabulin and pegfilgrastim was 0.524 day

Exploratory

- Clinical sequelae of CIN were comparable or slightly better for plinabulin vs pegfilgrastim.
- Plinabulin caused less bone pain (p=0.01) and lower mean change in platelet count from baseline (p<0.0001 on D15) vs pegfilgrastim.

