

Abstract #533: Chemotherapy Induced Profound Neutropenia (PN) in Patients (pts) with Breast Cancer (BC) after chemotherapy and Plinabulin (Plin) plus Pegfilgrastim (Peg) Combination versus (vs) Peg Alone. Final Phase 3 Results from PROTECTIVE-2 (BPI-2358-106)

Authors: Yuankai Shi MD: National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China; Douglas Blayney MD FASCO: Stanford Cancer Institute, California, USA; Hryhorii Adamchuk MD: MI Kriviy Rih Oncology Dispensary, Kriviy Rih, Ukraine; Qingyuan Zhang MD: Harbin Medical University Cancer Hospital, Harbin, China; Lihua Du: Wanchun Bulin Pharmaceuticals Limited, Dalian, China; Lan Huang PhD, Ramon Mohanlal MD PhD: BeyondSpring Pharmaceuticals, New York, USA.

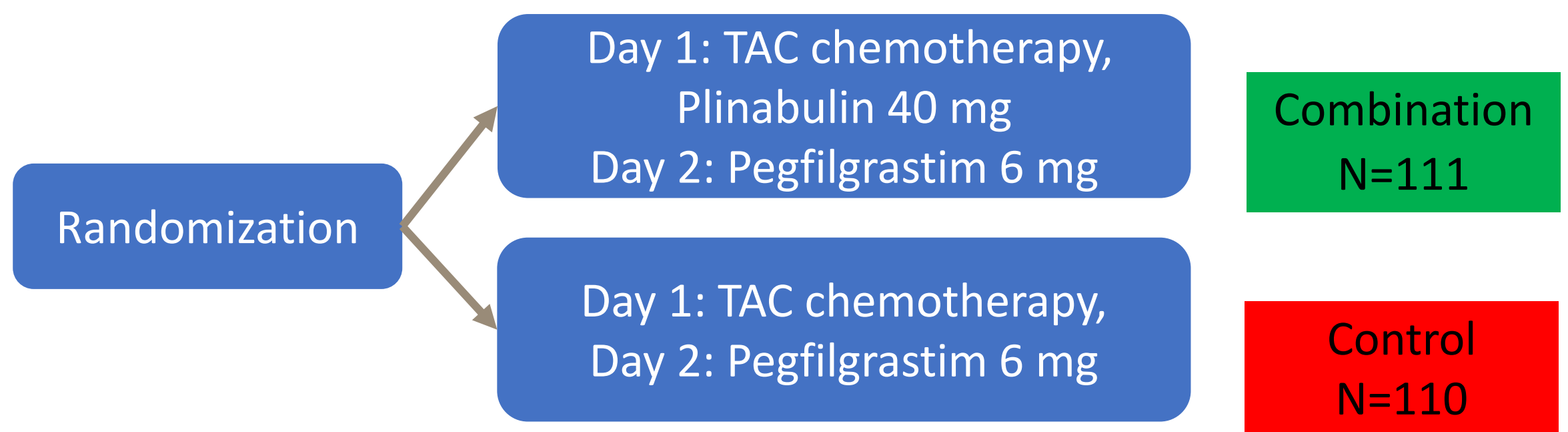
BACKGROUND

- Profound Neutropenia is the most severe form of chemotherapy-induced neutropenia (CIN) leading to 80% death in first week of infection¹.
- Pegfilgrastim is standard of care for the prevention of CIN.
- Pegfilgrastim has a slow onset of action ANC recovery occurring in Week 2 of the cycle, leaving patients vulnerable in the first week of the cycle.
- Plinabulin exerts its CIN preventive effects predominantly in Week 1 of the cycle.
- Combining Plinabulin with Pegfilgrastim can result in superior CIN protection throughout the entire cycle.

1. Bodey et al. Ann Intern Med 64(2):328

SUDY DESIGN

PROTECTIVE-2 (NCT03294577) is a global, multicenter, randomized, double-blind study to evaluate severe neutropenia.



PRIMARY OBJECTIVE (Cycle 1)

- To demonstrate superiority in CIN prevention of Plinabulin/Pegfilgrastim combination vs Pegfilgrastim alone for the absence of Grade 4 neutropenia.
- These data are presented in ASCO 2021 Poster #533

SECONDARY OBJECTIVES (Cycle 1)

- Mean DSN, Mean ANC Nadir

EXPLORATORY OBJECTIVES (Cycle 1)

- Profound Neutropenia

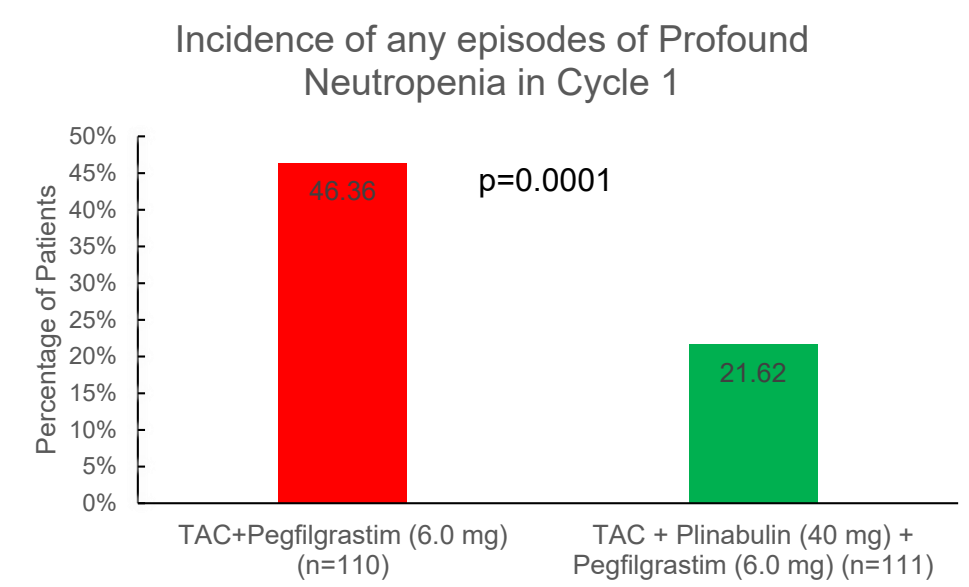
KEY FINDINGS

- **The Combination of Plinabulin/Pegfilgrastim Reduced Profound Neutropenia (PN):**
 - ✓ >50% reduction in incidence of PN (21.6% vs. 46.4%, p=0.0001)
 - ✓ 50% reduction in duration of PN (0.3 vs. 0.6 days, p=0.0004)
- **The Combination of Plinabulin/Pegfilgrastim improved clinical outcomes of CIN**
 - ✓ Rate of Febrile Neutropenia was lowered from 13.7% to 4.2% in patients with Profound Neutropenia
 - ✓ Rate of Hospitalization rate was lowered from 11.8% to 8.3% in patients with Profound Neutropenia

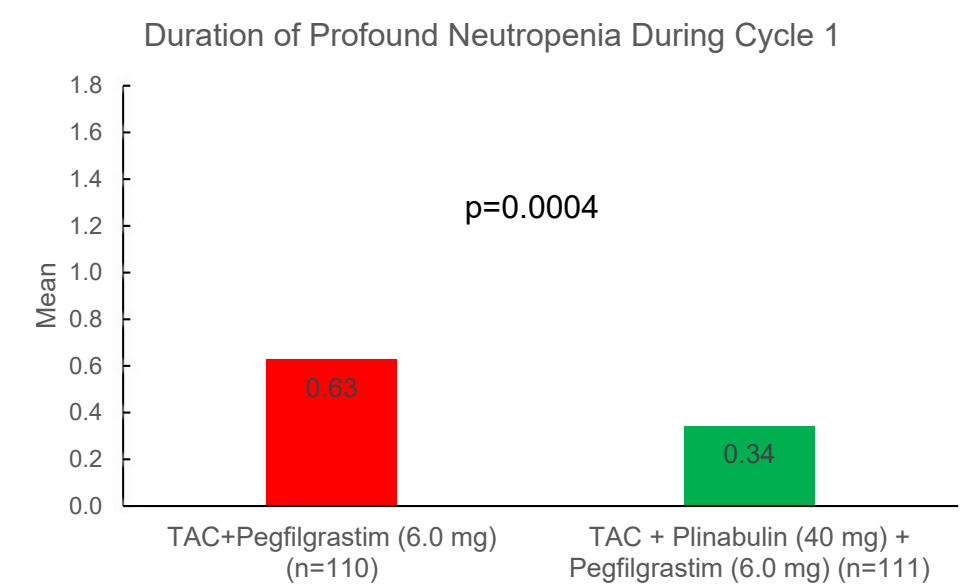


Corresponding Authors:
 Yuankai Shi, MD – syuantkai@cicams.ac.cn
 Ramon Mohanlal, MD, PhD - rmohanlal@beyondspringpharma.com

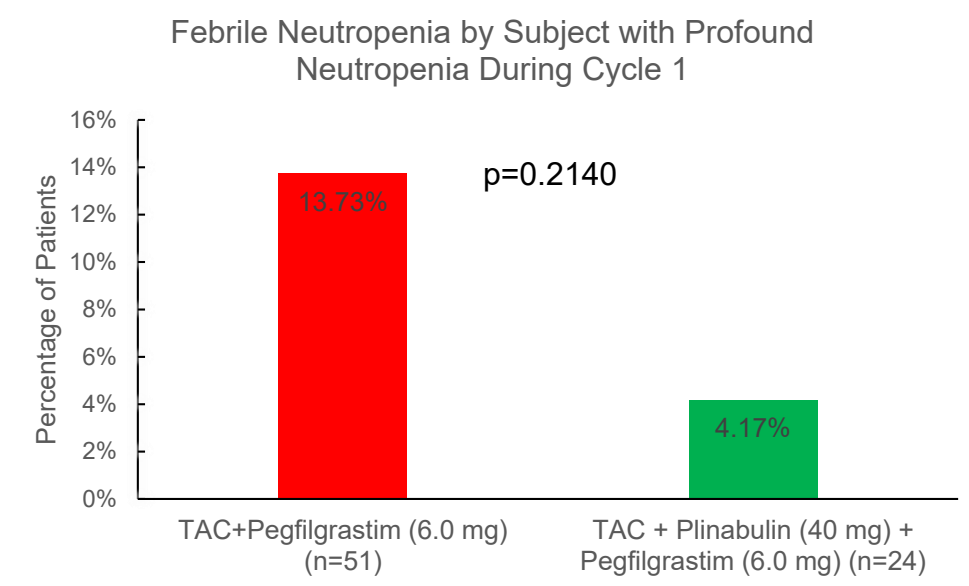
RESULTS



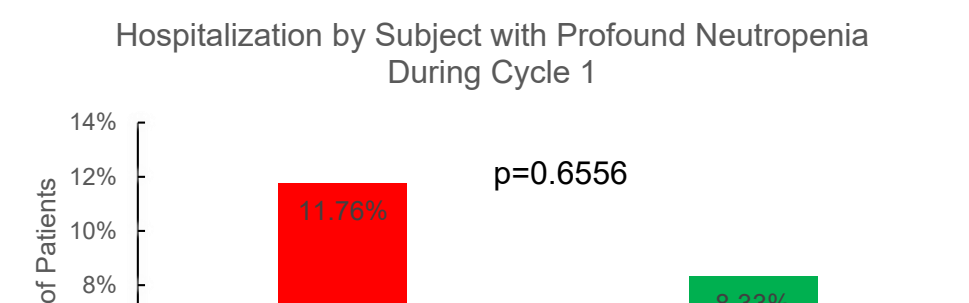
The Plinabulin/Pegfilgrastim arm showed lower frequency of Profound Neutropenia



Lower mean Duration of Profound Neutropenia



Study demonstrated Less Febrile Neutropenia in patients with PN



Fewer Hospitalizations in patients with PN