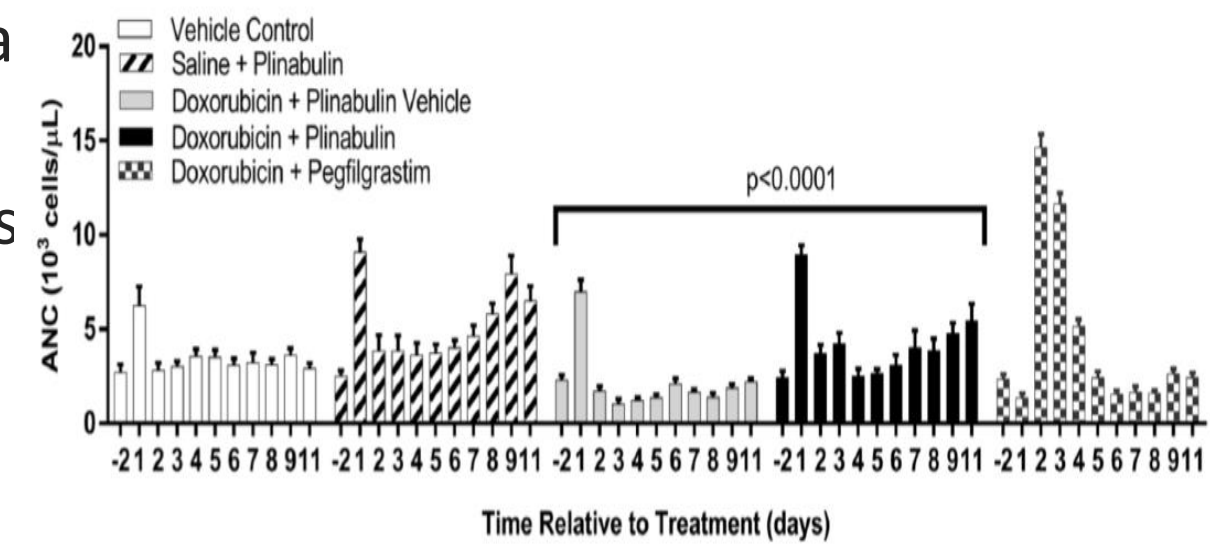


Head-to-head comparison of the non-G-CSF small molecule single agent (SA) Plinabulin with SA pegfilgrastim for the prevention of docetaxel chemotherapy (chemo)-induced neutropenia (CIN) in the protective-1 trial.

Douglas W. Blayney, MD, Ramon Mohanlal, MD PhD, Lan Huang, PhD, for the International Plinabulin CIN Study Group

Plinabulin – Why study in chemotherapy induced neutropenia?

- Small molecule
- Inexpensive to manufacture
- Given by IV infusion on same day as chemotherapy
- Serendipitous observation of less WBC toxicity in NSCLC Phase 2
- Potential anti cancer efficacy

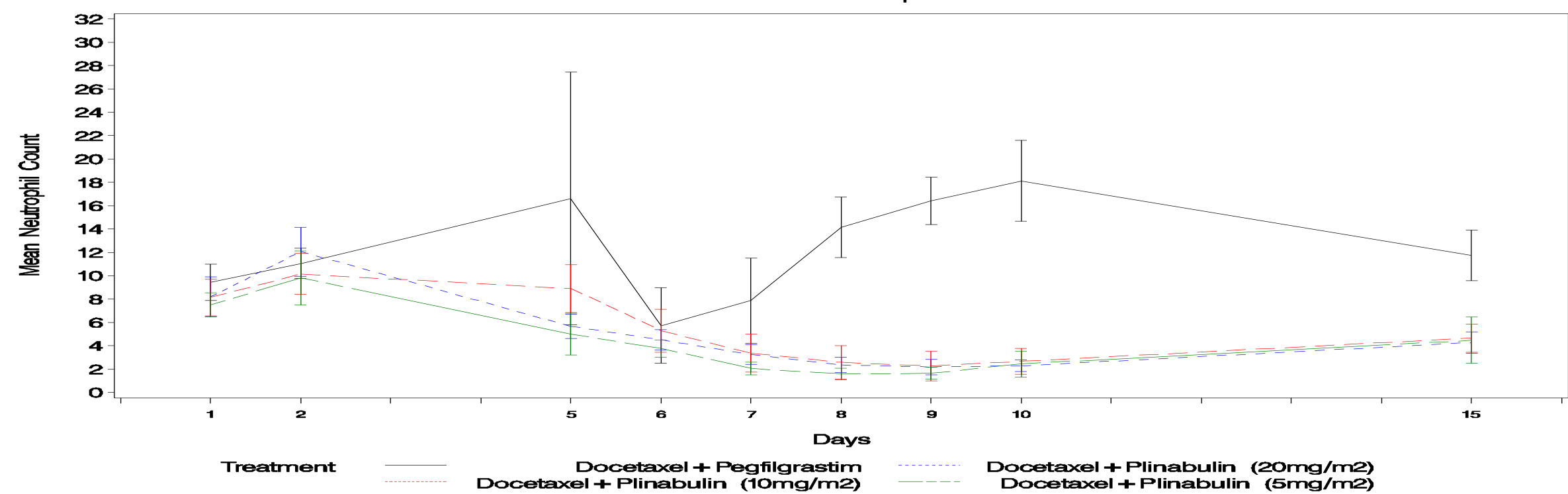


Results of Protective-1 Phase 2: Intermediate FN Risk

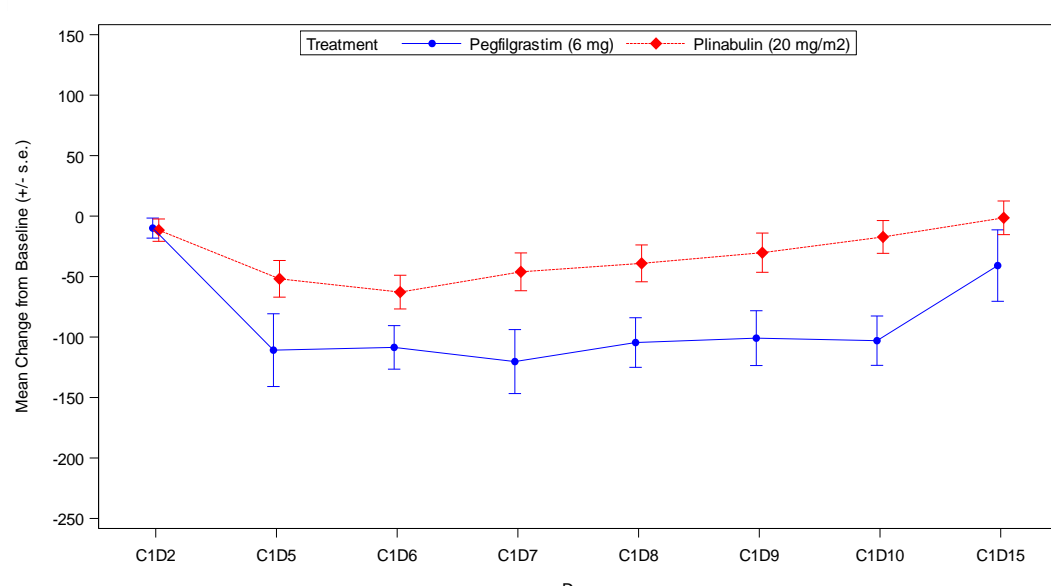
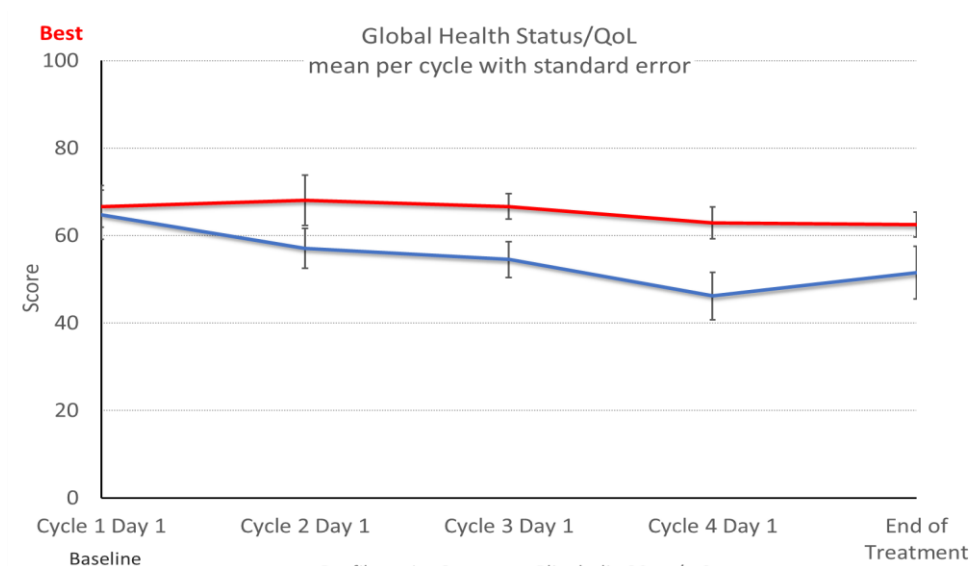
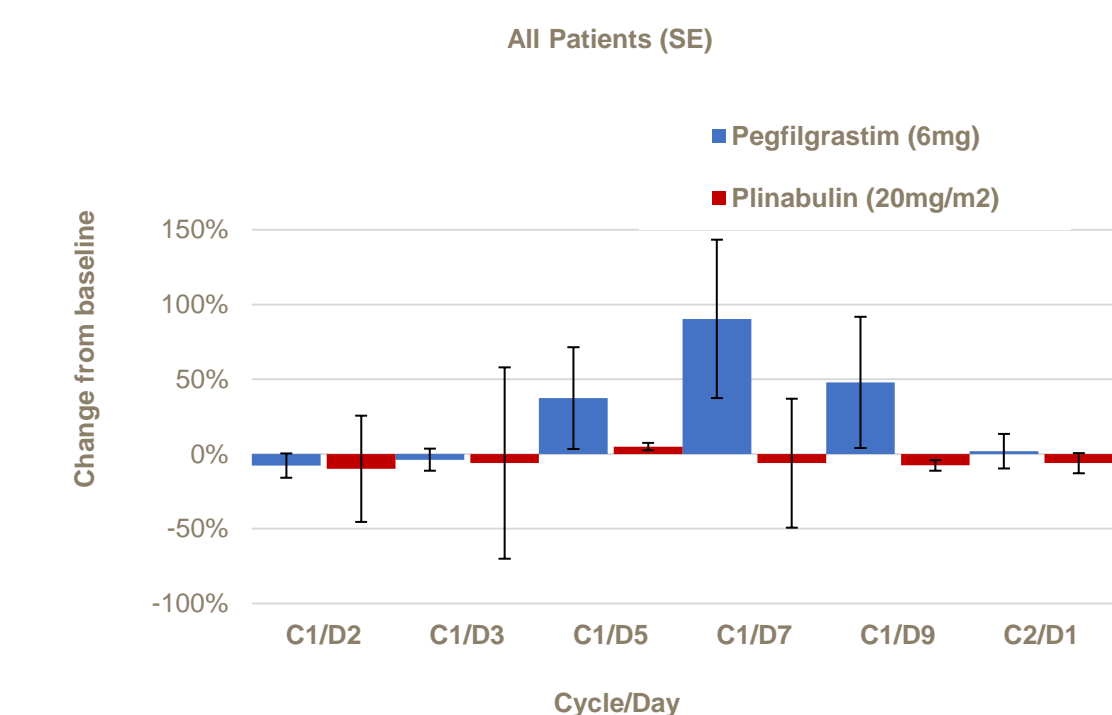
Equal Days of Severe Neutropenia (DSN)

Tonra et al., 2019

PROTOCOL BPI-2358-105
T2 Figure 16.2: Plot of the Mean (95% CI) Absolute Neutrophil Count (ANC) by Time and Treatment Group
Parameter = Absolute Neutrophil Count



Plinabulin 20mg/m2 with less Bone pain and Thrombopenia, better Quality of Life



Trial in Progress: Plinabulin Day 1 vs pegfilgrastim Day 2 in intermediate Febrile Neutropenia risk Docetaxel 75 mg/m² Day 1

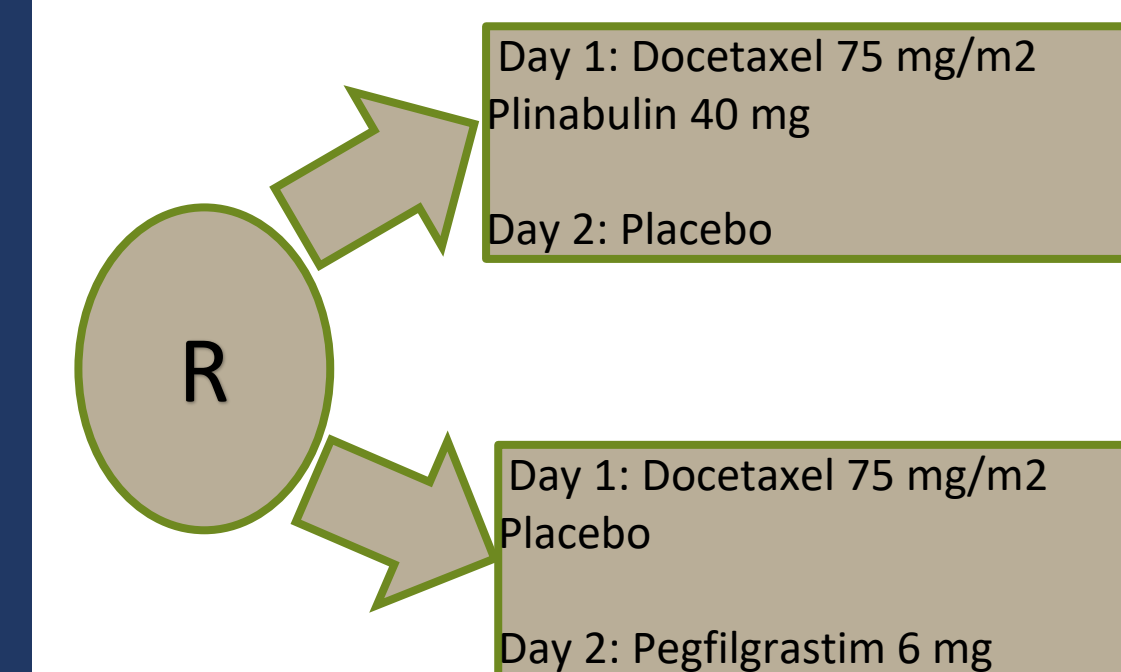
■ Powered to establish Plinabulin 40 mg fixed dose, same day as chemotherapy, with non-inferior DSN to pegfilgrastim

■ Same day infusion with less “touches” to health care system (important in time of COVID-19 pandemic)



Protective-1, phase 3: Intermediate FN Risk

- Lung, breast, prostate cancer
- Docetaxel 75 mg/m² x 4 cycles
- High FN risk (age>65, previous chemo or XRT, surgery within 4 weeks, tumor in marrow)



- Primary Endpoint
 - Days Severe Neutropenia
- Secondary Endpoint
 - Bone pain
 - Thrombocytopenia
 - NLR
 - Grade 4 neutropenia
 - Incidence of infection

Protective-1 Phase 3

- Powered to establish Plinabulin 40 mg fixed dose, same day as chemotherapy non-inferiority DSN as Pegfilgrastim
 - Intermediate (10-20%) FN risk
 - NCCN Guidelines do not suggest primary prophylaxis for Intermediate FN Risk chemotherapy
 - Recent change of NCCN guideline to have COVID-19 as one risk factor, so suggest to use G-CSF prophylaxis
 - Plinabulin monotherapy potential advantage over G-CSF
 - Same day infusion with less “touches” to health care system (important in time of COVID-19 pandemic)
 - May reduce hospital bed demand
 - Rapid onset of action in week 1
 - Less Thrombocytopenia
 - Less Bone Pain
 - Better Quality of Life