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Plinabulin is a more Favorable Option for the Prevention of Chemotherapy Induced Neutropenia (CIN)

than Pegfilgrastim during the COVID-19 Pandemic.

Douglas W. Blayney, MD¹; Lan Huang, PhD²; Ramon W. Mohanlal, MD, PhD, MBA² ¹Stanford Cancer Institute, ²BeyondSpring Pharmaceuticals Inc., New York, NY



Introduction

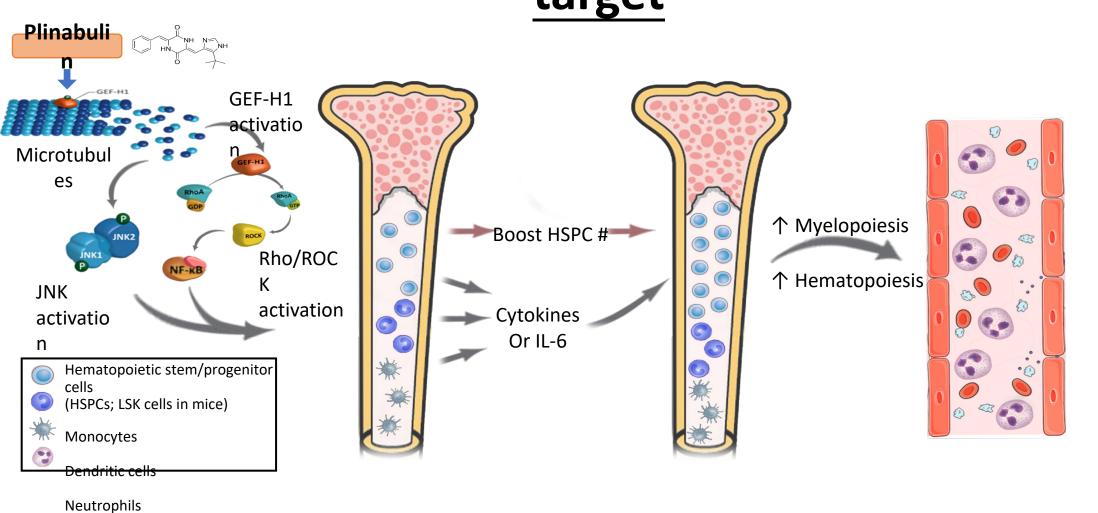
- Due to COVID-19, the NCCN Myeloid Growth Factor Panel expanded prophylactic G-CSF use to chemotherapy with Intermediate Risk (10%-20% risk) of Febrile Neutropenia (FN), and to Low Risk FN patients (pts) who previously developed FN.
- Preservation of resources for COVID-19 pts by reducing hospitalizations and emergency room visits by cancer chemotherapy pts is the intent of these changed recommendations.
- Other recommendations include use of self-injecting or on-body injector Pegfilgrastim, to minimize COVID-19 exposure at outpatient center by cancer pts and limiting prophylactic platelet transfusion to preserve blood product supply.
- Plinabulin is an attractive alternative: it is a novel, non-G-CSF small molecule with CIN protection comparable to Pegfilgrastim, is given once 30 minutes after Chemo, and avoids the need for healthcare system touches on Day 1-3 for G-CSF administration.
- In contrast to Pegfilgrastim, Plinabulin does not cause bone pain and thrombocytopenia and maintains quality of life.

Methods

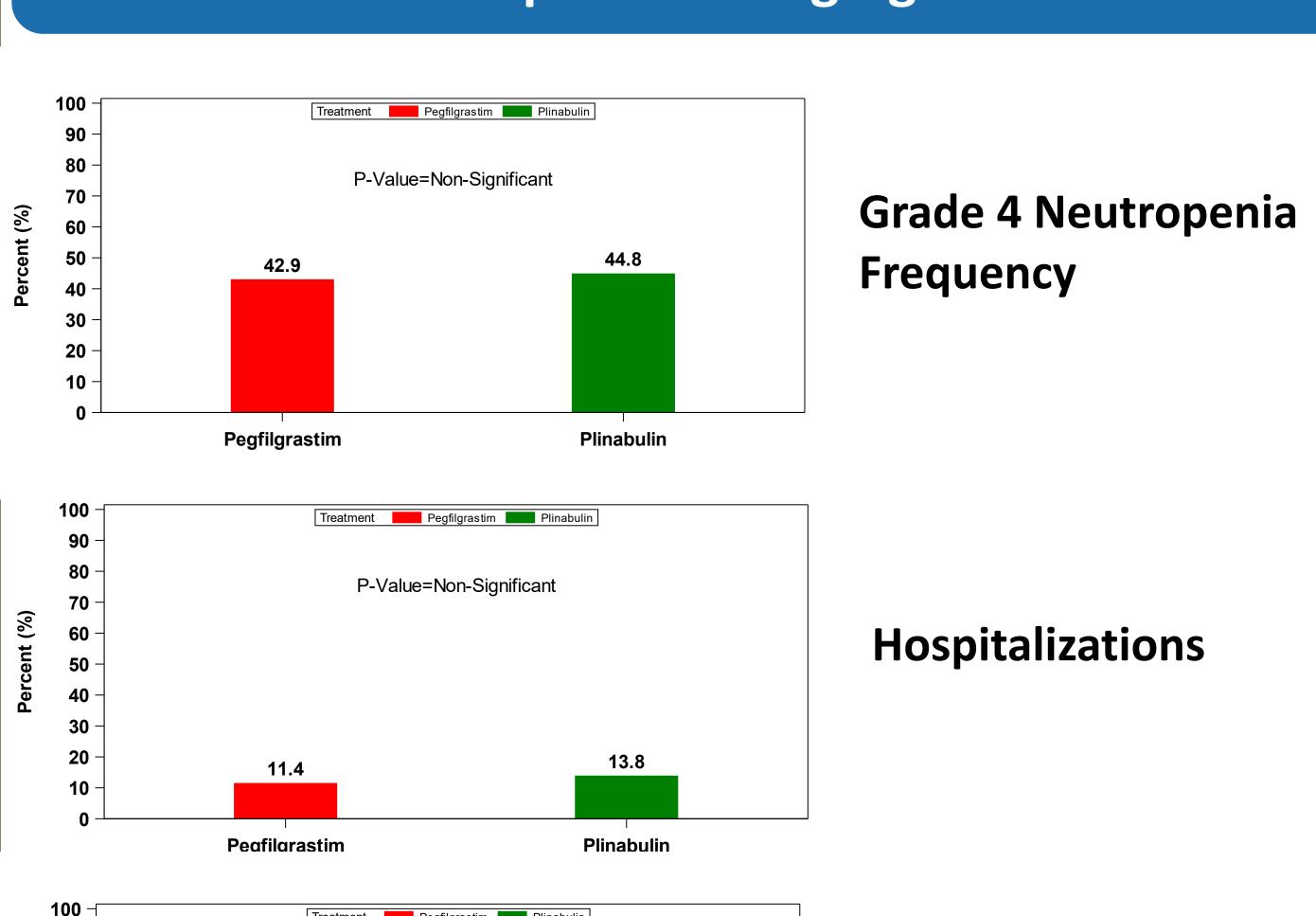
- We compared CIN data with single agent Plinabulin 20 mg/m2 (n=29) vs single agent Peg 6mg (n=35) from 2 different Phase 2 CIN studies over 4 cycles were done.
- Study 105 (NCT03102606) in NSCLC patients given Intermediate FN Risk Docetaxel 75 mg/m2 patients with risk factors), and,
- Study 106 (NCT03294577) in Breast cancer pts given High FN Risk Doc +Doxorubicin 50 mg/m2 + Cyclophosphamide 50mg/m2 (TAC).
- Plinabulin was given as a single IV infusion on Day 1, 30 min after the last Chemo, and Pegflgrastim 6mg given on Day 2 by SC injection.
- Grade 4 Neutropenia, Hospitalizations, Infection rate, Sepsis, all Grade, Grade 2/3 Thrombocytopenia Bone Pain is summarized for single agent Plinabulin and Pegfilgrastim

Plinabulin Mechanism of Action

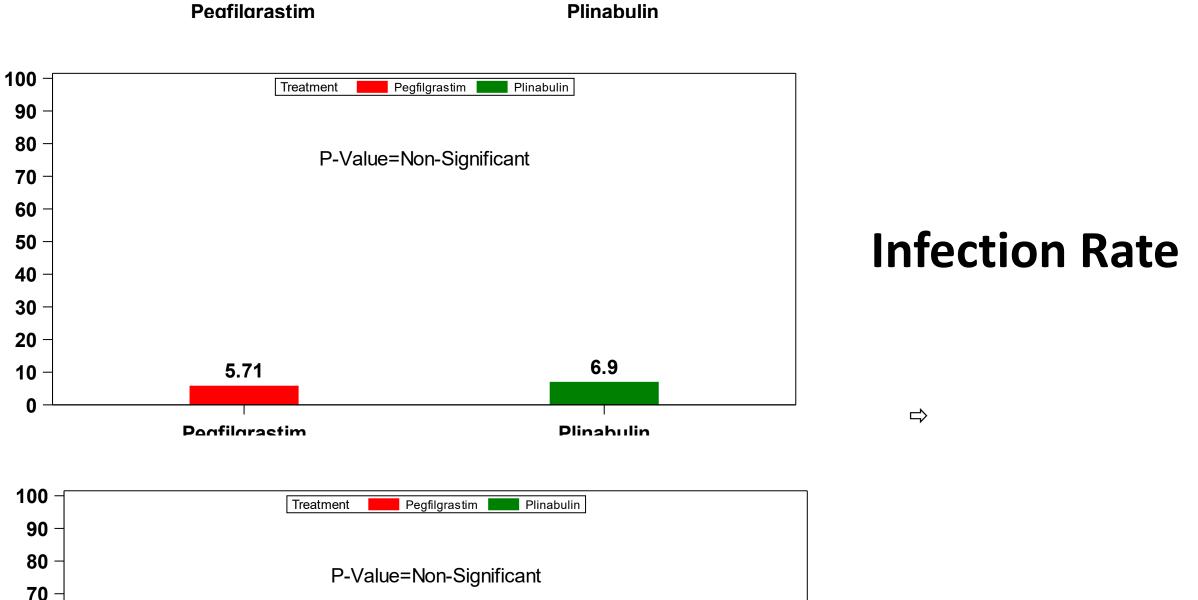
MoA - Plinabulin - First-in-Class Agent with GEF-H1 as a new target



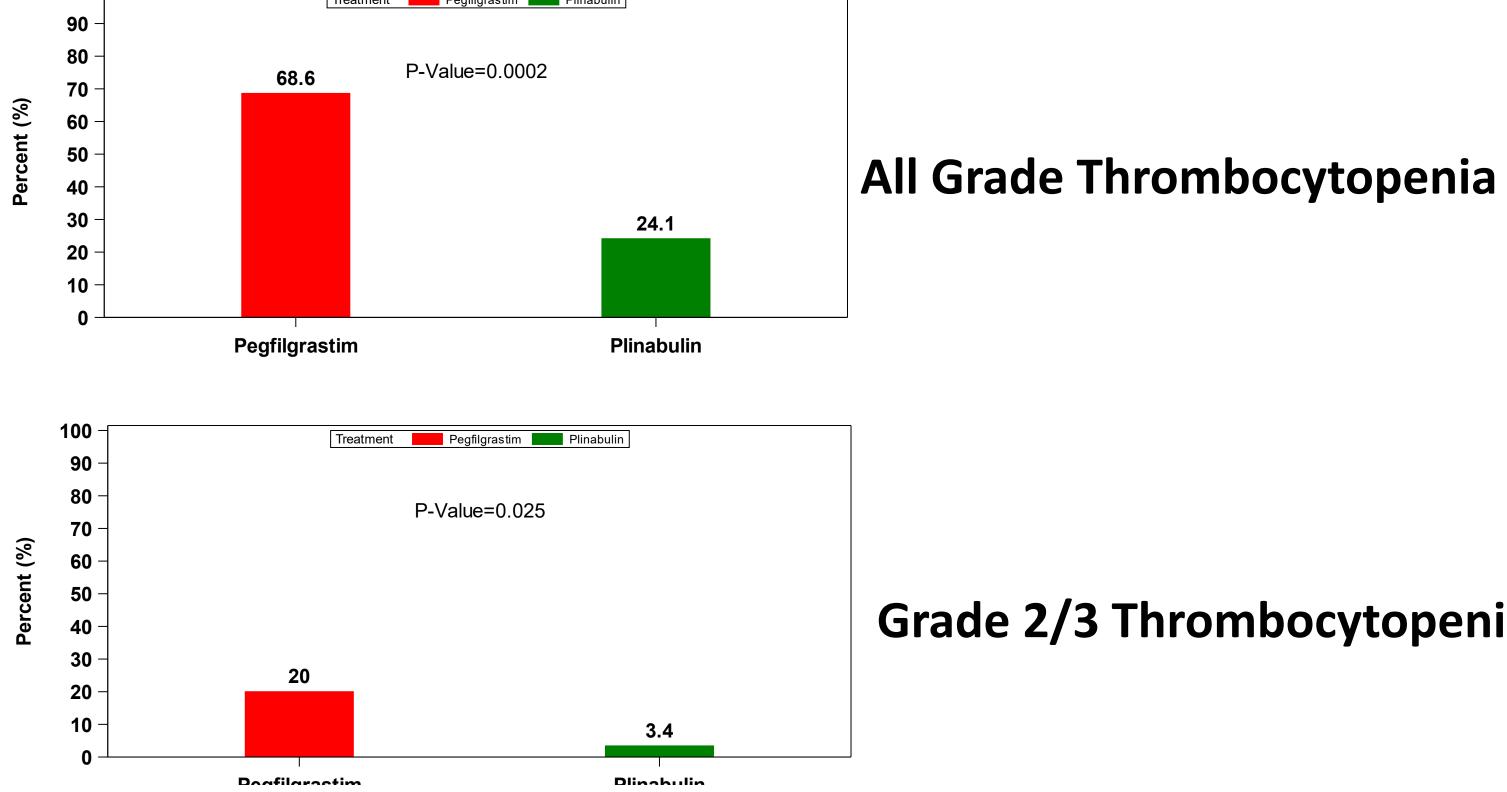
Fewer Neutropenic Complications with Plinabulin **Compared to Pegfilgrastim**



Hospitalizations



Sepsis

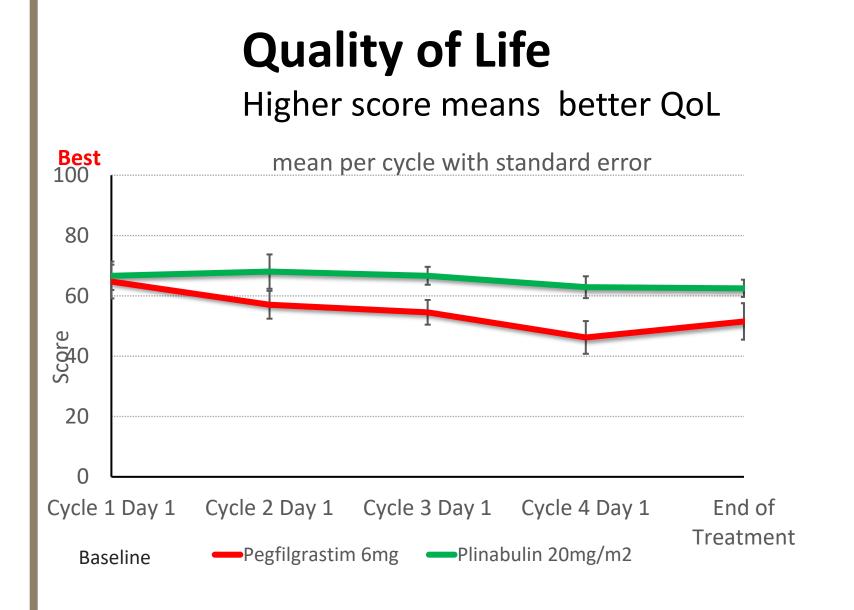


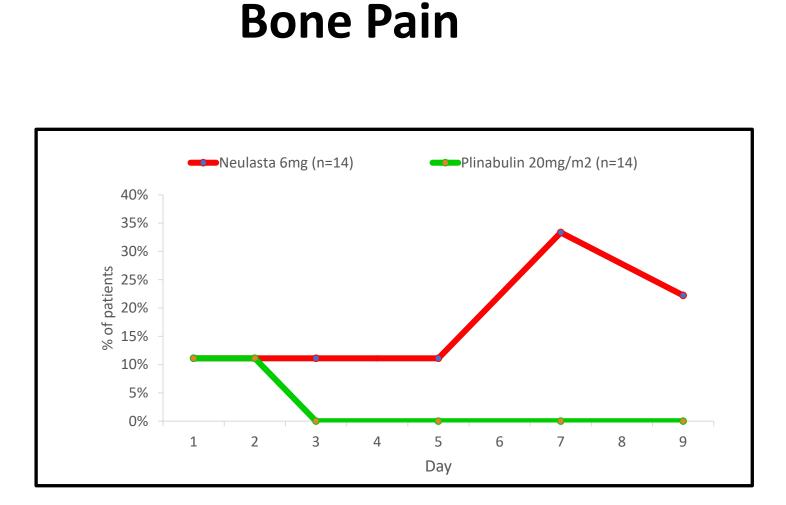
P-Value=0.06

Grade 2/3 Thrombocytopenia

Grade 3 Thrombocytopenia

Plinabulin Has Better Quality of Life and Less Bone Pain compared to Pegfilgrastim





Plinabulin Key Messages

- **▶**Plinabulin is NOT a -G-CSF Plinabulin is currently given as a fixed 40 mg dose
- ➤ Plinabulin is given on Day1: The <u>Same Day</u> of Chemo, 30 min after Chemo ➤ G-CSF is given on Day 2: The Next Day after Chemo
- > Plinabulin has Comparable Efficacy for Grade 4 Neutropenia, Hospitalizations, Infection Rate and Sepsis vs Pegfilgrastim
- > Plinabulin has less Thrombocytopenia and less Bone Pain vs Pegfilgrastim
- > Plinabulin maintains QoL, whereas Pegfilgrastim decreases QoL
- > Plinabulin has Anti-Cancer Activity

Conclusion

- > The Same Day Dosing on the Day of Chemo Reduces Health Care Touches with 50% with Plinabulin vs Pegfilgrastim
- ▶ Plinabulin and Pegfilgrastim Have Comparable Efficacy for CIN and Clinical Sequelae of CIN but a Superior Profile for Bone Pain, QoL and Platelet Counts.

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> We have initiated an Expanded Access Program (EAP) to make Plinabulin available to Physicians/ Oncologist. If interested, please contact us at: <u>EAP@beyondspringpharma.com</u>

Disclosures: The first author received project support to his institution, and travel support from BeyondSpring during the conduct of the study. Dr Huang and Dr Mohanlal are employees of BeyondSpring Pharmaceuticals

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