**ABSTRACT 21-A-613-SABCS**

Mechanistic evidence associated with the benefit of plinabulin significantly reducing bone pain in breast cancer patients (pts) treated with TAC (Docetaxel, Doxorubicin, Cyclophosphamide) and Pegfilgrastim (Peg)

Douglas W. Blayney1, Stephan Ogenstad2, Mengru Chang3, Yvette Lelorier3, Lan Huang3 and Ramon Mohanlal3

1Stanford Cancer Institute, Stanford, CA; 2Statogen Consulting, LLC, Wake Forest, NC; 3BeyondSpring Pharmaceuticals Inc, New York, NY

**BACKGROUND**

- Pts with breast cancer (BC) who receive chemotherapy (chemo) are frequently treated with granulocyte colony-stimulating factor (G-CSF) therapies including pegfilgrastim (Peg) to mitigate chemotherapy-induced neutropenia (CIN) (Molineux, 2003)
- Peg treatment is associated with bone pain in a significant number of pts (Kirshner, 2018)
- It is unknown if severity of bone pain correlates with neutropenia

**OBJECTIVE**

To investigate the relationships between Plin and Peg activity, bone pain, and neutropenia in pts with breast cancer (BC)

**METHODS**

- PROTECTIVE-2 was a randomized, double-blind study that compared Peg with Peg + Plinabulin (Plin) in pts with breast cancer (Blayney ASCO 2021 No. 547)
- Treatment with Plin caused less bone pain than did Peg (P=0.01; PROTECTIVE-1; NCT03102606) (Blayney ASCO 2021 No. 547)
- Plinabulin (Plin) is a novel, non-G-CSF agent that also prevents CIN (SIMBA)
- It is unknown if severity of bone pain correlates with neutropenia

**RESULTS**

- Pts treated with pegfilgrastim + plinabulin experienced less bone pain than did pts treated with pegfilgrastim only
- Mean Bone Pain Score
  - TAC + Pegfilgrastim (6.0 mg) + Plinabulin (40 mg) (n=57)
  - TAC + Pegfilgrastim (6.0 mg) (n=110)
  - TAC + Plinabulin (40 mg) + Pegfilgrastim (6.0 mg) (n=111)

- Mean ANC Nadir
  - TAC + Pegfilgrastim (6.0 mg) + Plinabulin (40 mg) (n=110)
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**ACKNOWLEDGMENTS**

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Dr Blayney has received project support to Stanford Cancer Institute, Stanford, CA, and travel support from BeyondSpring Pharmaceuticals. DJC has received support from Beyondspring Pharmaceuticals, Inc.

All authors are employees of BeyondSpring Pharmaceuticals, Inc, NY.

**CONCLUSION**

Adding Plinabulin to Pegfilgrastim reduces bone pain due to mitigating the depth of the ANC nadir among pts with BC receiving TAC

**TREATMENT-EMERGENT ADVERSE EVENTS OF BONE PAIN, CYCLES 1 TO 4**

- Bone Pain Scores by Day, Cycle 1 Days 1 to 21
- Mean ANC Nadir by Day, Cycle 1 Days 1 to 15

**TREATMENT-EMERGENT ADVERSE EVENTS OF BONE PAIN, CYCLES 1 TO 4**

- Treatment-emergent Adverse Events of Bone Pain, Cycles 1 to 4
  - 0.00%
  - 18.02%
  - 30.00%

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