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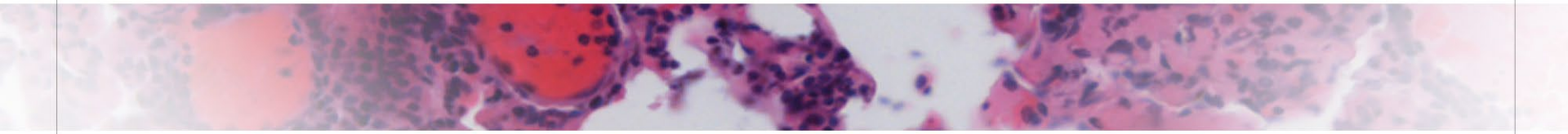

PROTECTIVE-2 (BPI-2358-106): A CONFIRMATORY TRIAL TO DEMONSTRATE SUPERIORITY OF THE PLINABULIN + PEGFLIGASTRIM (PLIN/PEG) COMBINATION vs STANDARD OF CARE PEGFILGASTRIM FOR THE PREVENTION OF CHEMOTHERAPY INDUCED NEUTROPENIA (CIN) IN BREAST CANCER PATIENTS

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BeyondSpring PHARMACEUTICALS

PROTECTIVE-2 (BPI-2358-106):
A Confirmatory Trial to Demonstrate Superiority of the Plinabulin + Pegfilgrastim (Plin /Peg) Combination versus Standard of Care Pegfilgrastim for the Prevention of Chemotherapy-Induced Neutropenia (CIN) in Breast Cancer (BC) Patients (pts)

PLINABULIN

Plinabulin is a novel, small molecule, non-G-CSF agent.

Given as a single dose per cycle, by 30 min IV infusion, 30 min after Chemotherapy

On the same day of Chemotherapy

BACKGROUND

- Plinabulin exerts its CIN preventive effects predominantly in week 1 of the cycle
- Pegfilgrastim Primarily exerts its CIN preventive effects in week 2 of the cycle
- Combined these two agents, to obtain superior CIN protection throughout the entire cycle (Blayney ASCO 2019).
- Data from Phase (Ph) 2 portion of PROTECTIVE-2 (NCT0329457) with the Plin/Peg combination demonstrated superiority in CIN protection vs Peg alone, with a favorable safety/tolerability profile (Blayney, St Gallen 2019).
- The Ph 3 portion of PROTECTIVE-2 aims to confirm superiority of the Plin/Peg combination vs Peg standard of care for avoidance of CIN and Bone Pain-prevention

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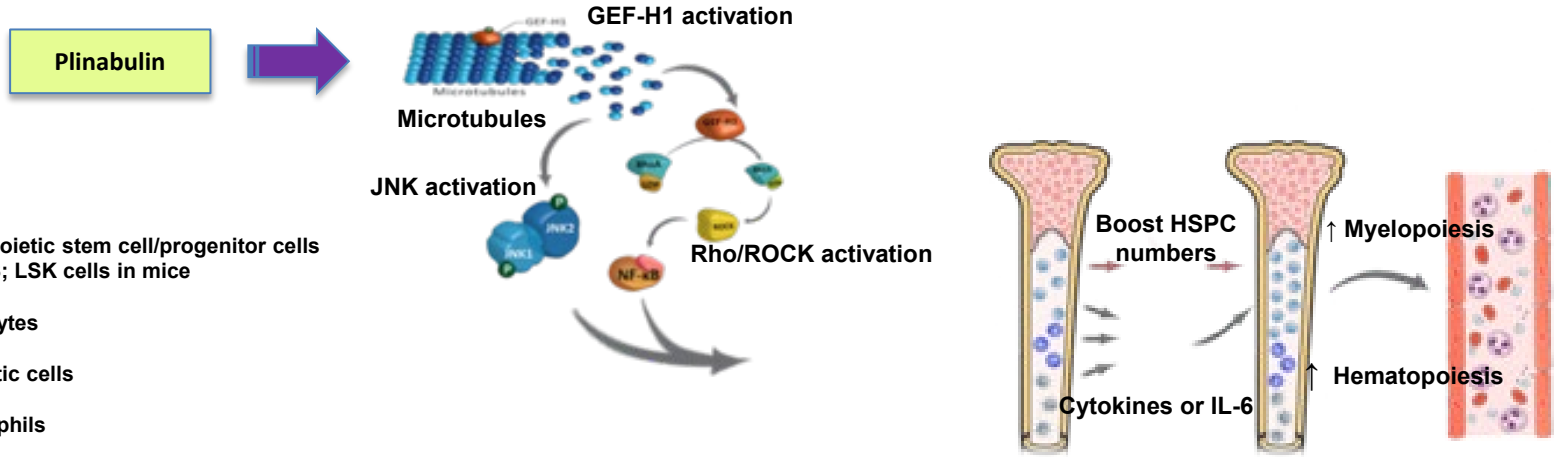
PLINABULIN MECHANISM OF ACTION

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



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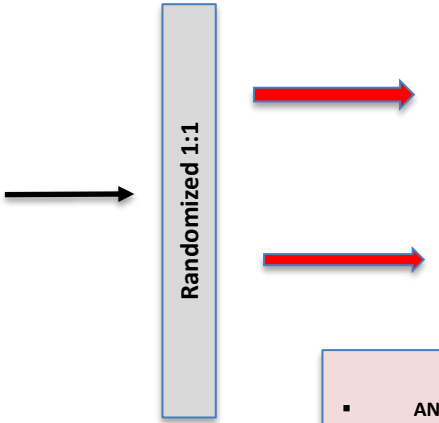
TRIAL DESIGN

PROTECTIVE-2
is a global, multicenter, randomized, double-blind study to Evaluate Severe Neutropenia.

- N =222
- Early stage (Stage I and II) and Stage III BC (node positive or node negative with a high risk of recurrence)
- ECOG status 0 or 1
- Receiving myelosuppressive Chemo with Docetaxel (75 mg/m2), Doxorubicin (50 mg/m2), and Cyclophosphamide (500 mg/m2) (TAC).



DATA COLLECTION METHOD

- **ANC (Covance Central Laboratory) was assessed before and after during Cycle 1 on D 1, 2, 3, 6, 7, 8, 9, 10, 11, 12, 13, and 15.**
- **Bone Pain was assessed by a validated & regular timepoints in Cycle 1 with a validated PRO questionnaire.**

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Primary objective

To compare the percentage of pts with a Duration of Severe Neutropenia (DSN) of 0 days in treatment Cycle 1 between the Plin /Peg vs Peg alone.

Secondary objectives:

In Cycle 1

- mean DSN,
- mean ANC NADIR,
- average change in Bone Pain from baseline,
- the rate of composite risk (infection, FN, hospitalization, significant disability, life threatening and death).
- Bone Pain

Over 4 Cycles,

- The percentage of patients with Relative Dose Intensity (RDI) < 85% and clinical sequelae of CIN (FN, Hospitalizations, Infection rate, Antibiotic use).

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TRIAL PROGRESS

Current Status: Patient accrual has been completed.

Final data read out in 2020.

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DISCLOSURE

- Dr Blayney has received project support to Standford Cancer Institute, Stanford, CA, and travel support from BeyondSpring during the conduct of the study.
- Dr Huang and Dr Mohanlal are employees of BeyondSpring Pharmaceuticals Inc, NY.

CONTACT THE AUTHORS

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