ABSTRACT 21-A-614-SABCS

# Combination Plinabulin+Pegfilgrastim (Plin+Peg) Had Better Toxicity Management and Health Related Quality-of-Life (HrQoL) Compared to Peg Alone in Early-stage Breast Cancer (BC) Patients (pts) Treated With Taxotere, Doxorubicin and Cyclophosphamide (TAC)

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## BACKGROUND

- Chemotherapy options for pts with BC include cyclophosphamide (C) + docetaxel (TC), doxorubicin (AC), or all three agents (TAC)
- Use of TAC improves survival, but it may increase toxicity and decrease HrQoL (Barcenas, 2014)
- Treatment with Peg (granulocyte colony-stimulating factor; G-CSF) decreases one measure of toxicity (neutropenia) (Crawford, 1991)
- Plinabulin (Plin) is a novel, non-G-CSF agent that improves neutropenia.(Blayney ASCO 2021 No. 547) Plin is a member of a new class of selective immunomodulating microtubule-binding agents (SIMBA)
- It is unknown if Plin+Peg have additive effects on toxicity and HrQoL

## OBJECTIVE

To examine the mitigating effects of Plin on toxicity and HrQoL among pts with BC also receiving Peg

## METHODS

- PROTECTIVE-2 was a randomized, double-blind study that compared Peg (n=111) to Plin+Peg (n=110) for pts with BC (Blayney ASCO 2021 No. 533)
- Patients received up to four, 21-day cycles of docetaxel 75 mg/m$^2$, doxorubicin 50 mg/m$^2$, and cyclophosphamide 500 mg/m$^2$ (TAC) with Peg 6 mg+Placebo or Plin+Peg (Peg 6 mg; Plin 40 mg)
  - Plin was given by 30-minute infusion 30 minutes after chemo
  - Peg was given subcutaneously 24 hours after chemo (Day [D]2)
- HrQoL was assessed by the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) and Euro Quality of Life 5 dimension, 5 level (EQ-5D-5L) questionnaires
- Pathological complete response (pCR) rate was assessed by evaluation of excised BC tissue after surgery
- Adverse events (AEs) were reported on case report forms
- Toxicity was evaluated by central laboratory assessments

## Adding Plinabulin to Pegfilgrastim Decreases Toxicity and Improves HrQoL Among Pts With BC Receiving TAC

## TAC Should Be Reevaluated for Pts with Early-stage BC In Light of the Improved Outcomes with Plinabulin+Pegfilgrastim Support

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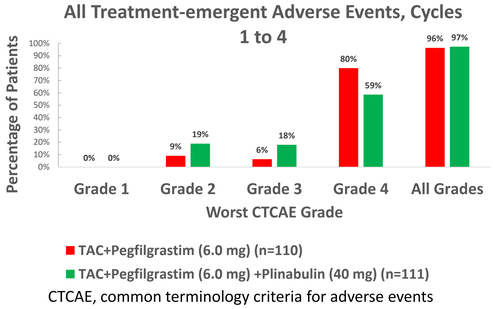
## RESULTS

**The adverse event (AE) profile among pts treated with plinabulin + pegfilgrastim was shifted towards lower grade AEs**

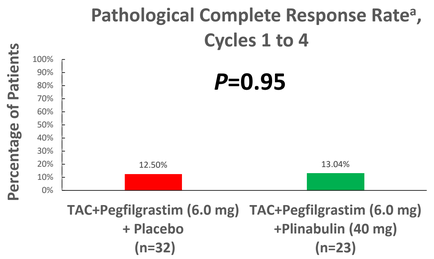



CTCAE, common terminology criteria for adverse events

### Plinabulin improves the toxicity profile of TAC

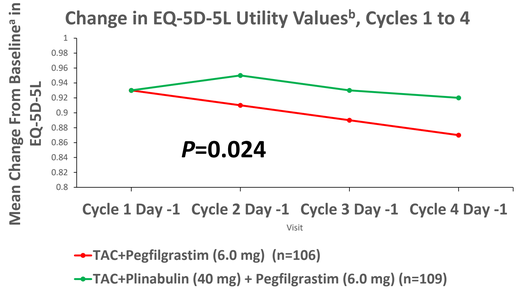
- Comparable overall AEs
- Less grade 4 AEs and shifting of grade 4 AEs to a lower grade

**Adding plinabulin to pegfilgrastim yielded similar pathological response rates**




[a] defined by local standard protocol

**Adding plinabulin to pegfilgrastim prevented a decline in HrQoL scores for mobility, self-care, daily activities, pain, and anxiety**




[a] Day -1, Predose
[b] United States Valuation of EQ-5D-5L Health States Using (Pickard 2019)