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Background: We assessed the occurrence of febrile neutropenia (FN) events and the associated healthcare resource use and costs of cancer patients receiving myelo-suppressive chemotherapy in combination with pegfilgrastim (PEG) versus lipogl- grastim (LI-PEG).

Methods: A retrospective analysis was conducted using a German insurance claims database. Adults receiving chemotherapy with a prescription code for PEG (n=734) or LI-PEG (n=346) between 2016-2017 were observed over a 1-year follow-up period. Patient subgroups were analysed according to cancer type (all types, breast, lung, lymphomas, neoplasms of the colon, pancreas, or stomach) and FN risk (overall, intermediate, high). FN risk was determined by a clinical expert by assessing the patients’ chemotherapy regimen received within the first 30 days of treatment. Outcomes were adjusted via regression analysis.

Results: In the PEG and LI-PEG groups, 30% (n=220) and 34% (n=119) of patients had intermediate FN risk, and 70% (n=514) and 66% (n=227) had high FN risk, respectively. The majority were female (PEG 77%; LI-PEG 80%) with a mean age of 58.2 years and 58.0 years. Across all cancer types during follow-up, 4.4% and 3.5% of patients receiving PEG or LI-PEG experienced a FN event. There were no significant differences in the mean numbers of FN events per patient for PEG (0.05) versus LI-PEG (0.04) across all cancer types. Annual mean neutropenia-related healthcare costs during follow-up were €603.61 and €441.35 for the PEG and LI-PEG groups; among patients with lymphomas, these costs were significantly greater (p=0.03) with PEG (€1,611.85) versus LI-PEG (€381.80). All-cause hospitalisations were significantly higher for lymphoma patients receiving PEG (2.76) versus LI-PEG (1.60). The occurrence of adjusted neutropenia-related hospitalisations was significantly higher for lymphomas than breast cancer (exponentiated coefficient [95% confidence interval]: 2.82 [1.16; 6.97]).

Conclusions: Unadjusted neutropenia-related healthcare costs and all-cause hospitalisations were significantly higher for lymphoma patients treated with PEG versus LI-PEG.

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Gr4N frequency had high exponential equation fit values with each: DSN (R²=0.647; n=3864; p<0.0001), FN rate (R²=0.44; n=4311; p<0.0001), ANC nadir (R²=0.37; n=2623; p<0.0001), hospitalization rate (R²=0.686; n=850; p<0.0001), and infection rate (R²=0.429; n=2042; p<0.0001). The criteria we used to satisfy the Gr4N threshold level to depict low risk for CIN outcomes was a DSN of <1 day (considered to be not clinically significant), and b) FN risk <10% (as defined by NCCN). The 65% Gr4N threshold met these criteria, as summarized below. For all CIN variables correlated with Gr4N, the curve stayed fairly flat between Gr4N of 0 to 65%, with an exponential rise after Gr4N>65%.

**Table: 1708P**

| Gr4N Frequency | Mean (95%CI), N | Gr4N ≥65% Mean (95%CI), N | P-value |
|----------------|----------------|---------------------------|---------|
| DSN            | 0.99 (0.97, 1.01), 2659 | 2.14 (2.08, 2.19), 2205 | <0.0001 |
| FN rate        | 4.50 (4.32, 4.68), 5168 | 3.61 (3.49, 3.73), 4528 | <0.0001 |
| ANC nadir      | 1.21 (1.08, 1.38), 1586 | 0.94 (0.82, 1.05), 1296 | <0.0001 |
| Hospitalization rate | 4.17 (3.70, 4.63), 435 | 15.93 (15.16, 16.70), 415 | <0.0001 |
| Infection rate | 4.38 (4.10, 4.66), 806 | 11.41 (10.39, 12.43), 1236 | <0.0001 |

**Conclusions:** Gr4N is a valid binary predictor of CIN outcomes and a 65% Gr4N threshold depicts low vs. high CIN outcome risk. Legal entity responsible for the study: BeyondSpring Pharmaceuticals Inc.

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**1709P**

**Prediction of febrile neutropenia (FN), hospitalization (Hosp), rates, and infection (Inf) rates in chemotherapy-induced neutropenia (CIN) patients (pts) treated with the plinabulin and pegfilgrastim combination (Plin+Peg) using a meta-analysis (MA)-based tool**

S. Ogenstad1, D. Blaney2, L. Huang3, R. Mohanlal1

1Ogenstad Consulting, LLC, Durham, NC, USA; 2Department of Oncology, Stanford University, Stanford, CA, USA; 3Clinical Research & Development, BeyondSpring Pharmaceuticals, New York, NY, USA

**Background:** Plinabulin is a novel non-G-CSF selective immunomodulating microtubule binding agent (SIMBA) developed for the prevention of CIN in conjunction with pegfilgrastim. QoL was analyzed using the Functional Assessment of Cancer Therapy – General questionnaire (FACT-G) and the EQ-5D-5L as part of a phase III (Ph3) clinical trial comparing pegfilgrastim to pegfilgrastim + plinabulin for prevention of neutropenia in newly diagnosed breast cancer patients being treated with docetaxel/dourubicin/cyclophosphamide (TAC).

**Methods:** Questionnaires were administered using ePRO app downloaded onto patients’ phones in Ukraine and China. Patients completed the FACT-G at Day D1, D1, DB and D15 and the EQ-SD-SL at D1, and D1. The FACT-G measured the impact of cancer in four categories: Physical wellbeing, Social wellbeing, Emotional wellbeing and Functional wellbeing, while the EQ-5D-SL measured health status in 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) rated from 1 (no problems) to 5 (extreme problems).

**Results:** Compared to pegfilgrastim alone, patients on plinabulin + pegfilgrastim performed significantly better for Physical wellbeing on DB and D15 of Cycle 2 (p=0.0589 and p=0.0039 respectively) and Cycle 3 (p=0.0360 and p=0.0343 respectively). Further analysis of the sub questions showed that both energy levels “I have a lack of energy” and “pain ‘I have pain’ were significantly better for the plinabulin + pegfilgrastim combination versus pegfilgrastim alone (p<0.0377 and p<0.0420 respectively). For the EQ-5D SL, patients on the plinabulin + pegfilgrastim combination remained stable over time while patients on pegfilgrastim alone deteriorated (p<0.0245). Observed compliance for FACT-G and EQ-SD-SL was 91% and 96% respectively.

**Conclusions:** The Physical wellbeing (in particular, pain and energy levels) of patients receiving plinabulin + pegfilgrastim was significantly less impacted by TAC compared to pegfilgrastim alone: recovering their pre-chemotherapy QoL wellbeing levels more rapidly and experiencing less deterioration in their QoL over the duration of the trial.

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**Table: 1709P**

| Gr4N Frequency | Mean DSN | FN rate | Hospitalization rate | Mean ANC nadir | Infection rate |
|----------------|----------|---------|----------------------|----------------|---------------|
| 86% (Peg Alone) | 3.01     | 24.3    | 20.6                 | 0.197          | 16.5          |
| 68% (Plin+Peg) | 1.66     | 10.1    | 8.29                 | 0.395          | 8.17          |
| p-value        | <0.0001  | <0.0001 | <0.0001              | <0.0001        | <0.0001       |