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baseline levels. All 22 subjects who started cycle 2 received full CPDOT. Of the 121 cycles delivered over the study, 107 (88%) were full CPDOT. In addition, 18 subjects (67%) received all their cycles according to full CPDOT. Of the 22 subjects who were assessed for disease response, 2 (9%) had CR, 15 (68%) PR (with ORR 77%) and 2 (9%) SD. Safety data were consistent with the underlying patient group. Nine (33%) and 6 (22%) subjects experienced hematological and non-

hematological events of toxicity grade 3-4: anemia 15%, leukopenia 7%, thrombocytopenia 11%, and febrile neutropenia 15%. All other adverse events were single episodes.

Conclusions

These results indicate that pegfilgrastim enables delivery of dose intensified ACE chemotherapy every 14 days in SCLC patients. ■

Abstract #8262

Palonosetron (PALO) Plus Aprepitant (APREP) and Dexamethasone (DEX)

For the Prevention of Chemotherapy-Induced Nausea and Vomiting (CINV) After Emetogenic Chemotherapy (CT)

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Background

PALO is the only 5-HT₃ receptor antagonist (RA) approved by the FDA for prevention of acute & delayed CINV after moderately emetogenic CT. Aprepitant is a NK₁ RA approved for prevention of acute & delayed CINV after highly emetogenic CT when used with a 5-HT₃ RA & DEX. We now report the first study combining these novel antiemetics in patients (pts) receiving a wide variety of moderately to moderate-highly emetogenic chemotherapy.

Methods

This multicenter, phase II, open-label study assessed the efficacy & safety of a single

IV dose of PALO 0.25 mg on Day 1 of CT, along with 3 daily oral doses of APREP (125 mg on Day 1; 80 mg on Days 2-3) plus DEX (12 mg on Day 1; 8 mg on Days 2-3). Eligible pts were naïve or non-naïve to CT. Efficacy assessments included complete response (CR: no emetic episodes [EE] and no rescue medication) and no EE during the acute (0-24 hr), delayed (24-120 hr), and overall (0-120 hr) intervals post-CT. Adverse events were collected to assess safety.

Results

Intent-to-treat assessments of the first 39 of the planned 50 pts are reported. Most

pts were women with breast cancer; 39% were chemo-naïve. The most common CT regimens were doxorubicin + cyclophosphamide and paclitaxel + carboplatin. (see table below) CR; no emetic episodes and no rescue medication. The most common adverse events included diarrhea, fatigue, and constipation, consistent with product labeling for PALO and/or APREP.

Conclusions

Preliminary results indicate that PALO, APREP, and DEX may be safely combined and may improve the overall prevention of CINV. ■

PALO + APREP + DEX	Acute (0-24 hr)	Delayed (24-120 hr)	Overall (0-120 hr)
CR, n (%)	35/39 (90%)	31/39 (80%)	31/39 (80%)
Pts with no EE, n (%)	38/39 (97%)	38/39 (97%)	38/39 (97%)