Efficacy

Primary Efficacy Endpoint: CR in the Acute Phase

CR, defined as the absence of emesis (vomiting or retching) for at least 24 hours after drug administration and no rescue medication in their diary for any reason, was assessed for the IV 30-min infusion group and the IV 30-sec bolus group.

Secondary Efficacy Endpoints: CR (delayed and overall)/no emesis/no rescue medication

CR rates in the delayed and overall phases were similar in the PALO 0.25 mg IV infusion group and the IV 30-sec bolus group (Figure 2).

Safety

The summary of TEAEs in patients receiving 0.25 mg PALO administered as an IV infusion bolus and IV 30-sec bolus is shown in Table 5.

CONCLUSIONS

Noninferiority of PALO 0.25 mg IV administered as a 30-min IV infusion compared with a 30-sec bolus was demonstrated.

Results of secondary analyses (ie, proportion of patients with no emetic episodes and of patients with no rescue medication) in the acute phase further support the noninferiority claim.

The proportion of patients with no emetic episodes in the acute, delayed, and overall phases was similar between the PALO 0.25 mg IV infusion and 30-sec bolus groups (Figure 3).

This study used real-world clinical practice data and was not designed to demonstrate noninferiority.

The frequency and severity of all reported TEAEs were similar for the IV 30-min infusion and IV 30-sec bolus groups.

The frequency of TEAE-related deaths was 0% in both groups.

There were no interruptions of the treatment among patients in the IV 30-min infusion group. No study drug-related death or severe drug reaction was reported.

Conclusion

Palonosetron (PALO) is a pharmacologically and clinically distinct second-generation 5-hydroxytryptamine-3 (5-HT3) receptor antagonist (5-HT3RA) approved for prevention of acute and delayed chemotherapy-induced emesis (CINV) and nausea and vomiting (N&V) induced by highly or moderately emetogenic chemotherapy (HEC).

Palonosetron (PALO) is the preferred 5-HT3RA for CINV prophylaxis in patients receiving HEC in antineoplastic guidelines from the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN).5,6

In antineoplastic guidelines from the Multinational Association of Supportive Care in Cancer (MASCC) European Society for Medical Oncology (ESMO) and the European Society for Medical Oncology (ESMO), PALO has been characterized as an effective alternative to the approved 30-sec IV bolus administration for the prevention of CINV in patients with malignant solid tumors undergoing chemotherapy (Figure 1).