A Randomized, Double-Blind Phase 3 Trial of Extended-Release Granisetron (APF530) Versus Palonosetron for Preventing Chemotherapy-Induced Nausea and Vomiting Associated With Moderately or Highly Emetic Chemotherapy: Does a Reanalysis Using Newer ASCO Emetogenicity Criteria Affect Study Conclusions?

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Abstract 9468

BACKGROUND

- The risk of chemotherapy-induced nausea and vomiting (CINV) is frequently reported in patients receiving moderately emetogenic chemotherapy (MEC) and >90% with highly emetogenic chemotherapy (HEC).

- Combination antiemetic regimens are used to treat nausea and vomiting in patients taking chemotherapy, for up to 91% of patients receiving moderately emetogenic chemotherapy (MEC) and 90% with highly emetogenic chemotherapy.

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METHODS

- For the phase 3 trial, 1350 (634 MEC, 716 HEC) were classified as at least MEC by ASCO reclassification criteria. There was no significant difference between APF530 and palonosetron in controlling acute CINV in patients receiving MEC or HEC; the higher dose was noninferior to palonosetron in preventing delayed CINV in patients receiving HEC.

RESULTS

- There were 175 patients in the safety population, of whom 1500 (MEC HEC) were classified at least MEC by ASCO reclassification criteria. There was no significant difference between APF530 and palonosetron in controlling acute CINV in patients receiving MEC or HEC; the higher dose was noninferior to palonosetron in preventing delayed CINV in patients receiving HEC.

CONCLUSIONS

- The original prespecified analysis of the phase 3 trial demonstrated noninferiority of APF530 in controlling acute CINV in patients receiving MEC or HEC, the higher dose was noninferior to palonosetron in preventing delayed CINV in patients receiving HEC as determined by CR after C1.

- Redosing chemotherapy emetogenicity by the new ASCO criteria did not alter the results from the original prespecified analysis regarding noninferiority to palonosetron in acute and delayed MEC and palonosetron in acute HEC (which was established) or superiority to palonosetron in delayed HEC (which was not established).

- However, redosing chemotherapy emetogenicity by the new ASCO criteria resulted in better CR rates in the MEC groups and poorer CR rates in the HEC groups for all arms of the study. This supports the ASCO redosification.

- Single-dose APF530 SC is an effective alternative to palonosetron for preventing acute and delayed CINV after MEC or HEC, with generally mild and manageable AEs.

REFERENCES


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