Phase 3 Study of APF530 Versus Ondansetron With a Neurokinin 1 Antagonist + Corticosteroid in Preventing Highly Emetogenic Chemotherapy-Induced Nausea and Vomiting: MAGIC Trial

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Abstract 68

Current antiemetic treatment guidelines recommend a 3-drug regimen for patients receiving HEC, comprising a 5-hydroxyptamine 3 receptor antagonist (5-HT3RA) and a corticosteroid, in addition to a benzodiazepine or a tri(ethylene glycol) polymer. APF530 (Granisetron Injection, Extended-Release) is a novel formulation of 2% granisetron and a bioerodible tri(ethylene glycol) polymer that provides sustained-release of granisetron for > 90% with highly emetogenic chemotherapy (HEC) and > 90% with moderately emetogenic chemotherapy (MEC) chemotherapy-induced nausea and vomiting (CINV) being 31% to 90% with moderately emetogenic chemotherapy and 0% to 5% with MEC chemotherapy. The modified intent-to-treat (mITT) population (received HEC and study drug, and had on-study treatment failure) of 902 patients was included in the mITT population (N = 459). APF530 500 mg SC injection was associated with less nausea compared with the ondansetron regimen. A post hoc analysis of nausea frequency was conducted that included treatment emergent adverse events (TEAEs) that were adverse events that began within days of study drug administration. This prospective, randomized, double-blind, double-dummy, multicenter phase 3 trial compared APF530 to ondansetron in preventing CINV following HEC in a 3-drug regimen versus a standard 3-drug regimen with ondansetron + dexamethasone (DXM). The MAGIC Trial compared the efficacy and safety of APF530 in preventing CINV following HEC in a 3-drug regimen versus a standard 3-drug regimen with ondansetron + dexamethasone (DXM).

APF530 (Granisetron Injection, Extended-Release)

APF530 is a novel formulation of 2% granisetron and a bioerodible tri(ethylene glycol) polymer. This study was designed with 90% statistical power for the primary end point comparison. Qualitative variables were analyzed using a Cochran-Mantel-Haenszel chi-square test controlled by use of cisplatin-based regimens ≥ 50 mg/m² and overall phases (P < 0.05). A post hoc analysis indicated that APF530 versus ondansetron was associated with less nausea compared with the ondansetron regimen.

CONCLUSIONS

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REFERENCES


