EMESIS RATE AND RESCUE MEDICATION USE IN CHILDREN USING AREPITANT TO PREVENT CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING (CINV)

H.J. Kang1, S. Loftus2, A. Taylor3, C. Dicristina4, S. Green5, C. Zwaan6
1Pediatrics, Seoul National University College of Medicine, Seoul National University Hospital, Seoul, KOREA
2Respiratory and Immunology, Merck & Co., Inc., North Wales, PA, USA
3Biostatistics and Research Decision Sciences, Merck & Co., Inc., Upper Gwynedd, PA, USA
4Clinical Development Execution Organization, Merck & Co., Inc., North Wales, PA, USA
5Clinical Research, Merck Research Laboratories, Kenilworth, NJ, USA
6Pediatric Oncology, Erasmus MC, Rotterdam, NETHERLANDS

Aim: Aprepitant, in combination with a 5HT3-antagonist and a corticosteroid, is indicated for prevention of CINV due to highly/moderately emetogenic chemotherapy (chemo) in adults. To evaluate aprepitant for CINV prevention in children, a phase III, randomized, double-blind, active-comparator study was conducted in pediatric patients (NCT01362530).

Methods: Patients ages 12-17 years (y) undergoing highly/moderately emetogenic chemo received aprepitant capsule 125 mg + ondansetron before chemo (Day 1) + aprepitant capsule 80 mg (Days 2-3), OR placebo (Days 1-3) + ondansetron (Day 1). Patients 6 months to <12 y old received aprepitant powder-for-suspension (PFS) 3 mg/kg (up to 125 mg) + ondansetron (Day 1) + aprepitant PFS 2 mg/kg (up to 80 mg) (Days 2-3), OR placebo (Days 1-3) + ondansetron (Day 1). The primary objective was to compare the aprepitant and control regimens in eliciting a complete response 25-120 hours (h) after chemo initiation. Exploratory endpoints included the proportion of patients with no emetic episodes (acute, 0-24 h; delayed, 25-120 h after chemo initiation), time to first vomiting, proportion of patients not requiring rescue medication, and time to first use of rescue medication during the overall phase (0-120 h).

Results: Efficacy and safety were evaluated in 152 aprepitant and 150 control patients. The proportion of patients experiencing no emetic episodes was higher in the aprepitant regimen vs the control regimen during both acute (71.1% vs 53.3%) and delayed (55.3% vs 28.0%) phases. The median time to first vomiting (overall) was significantly longer for aprepitant vs control (94.5 vs 26.0 hours; P < 0.0001). The proportion of patients not requiring rescue medication use was higher for aprepitant vs control (66.4% vs 48.7%), and the time to first rescue medication use was longer for aprepitant vs control (P = 0.0024). Adverse events were similar between regimens and consistent with those in patients undergoing chemo.

Conclusions: In pediatric patients with cancer receiving emetogenic chemo, the 3-day aprepitant regimen prevented emetic episodes and reduced the need for rescue medication compared with a 5HT3-antagonist regimen without aprepitant.

Disclosure: H.J. Kang: Received research funding from Merck & Co., Inc. MK869 PN208 study involvement; S. Loftus: Full-time employee of Merck & Co., Inc., with stock ownership; A. Taylor: Full-time employee of Merck & Co., Inc.; C. Dicristina: Full-time employee of Merck & Co., Inc.; S. Green: Full-time employee of Merck & Co., Inc., with stock ownership. All other authors have declared no conflicts of interest.