BACKGROUND

- Chemotherapy-induced nausea and vomiting (CINV) is common in patients with cancer experiencing CINV and is often poorly controlled.
- An important risk factor for CINV is the emetogenicity of the chemotherapy regimen; the more emetogenic the chemotherapy regimen, the greater the incidence of CINV.

METHODS

- The study was a randomized, double-blind, placebo-controlled, parallel-group, multinational, multinational, multicenter, phase 3 study of healthy males and females between 18 and 75 years old to evaluate the efficacy and safety of a single SC dose of APF530 500 mg in preventing acute and delayed CINV in patients receiving MEC.

RESULTS

- Subjects
  - 113 of 130 randomized subjects completed the study.
  - 144 randomized subjects (AUB: 72), and 117 randomized treatment B (AUB: 65).
  - 9 discontinued from the study, none due to an AE.
  - Subjects crossed over on day 15 to receive APF530 via the other route.

- Bioavailability
  - 113 of 130 randomized subjects included were evaluated for pharmacokinetic analysis.
  - The 2 routes of administration were bioequivalent, providing ≥ 120 hours of granisetron exposure.
  - Granisetron levels for over 5 days (>120 h).

- Safety
  - 9% of 115 subjects receiving subcutaneous injections (treatment A) and 77% of 117 subjects receiving arm injections (treatment B) experienced a treatment-related AE.
  - The majority of TEAEs were mild or moderate (Table 2).
  - Numerous serious AEs occurred, but all were considered to be related to study drug (Table 3).

CONCLUSIONS

- APF530 administration in the ULC arm and the nondominant upper arm showed bioequivalence with no clinically relevant differences observed between treatment sites.

REFERENCES

4. Optimizum AB. QPS Bio-Kinetic, LLC, Springfield, MO; QPS, LLC, Newark, DE; Drug Safety Navigator, LLC, Durham, NC.