**APF530: A Novel Extended-Release Formulation of Granisetron for 5-Day Prevention of Chemotherapy-Induced Nausea and Vomiting (CINV)**

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**BACKGROUND**  
- Poorly controlled chemotherapy-induced nausea and vomiting (CINV) adversely affects patient quality of life.
- Chemotherapy agents are classified by their emetogenicity: highly emetogenic chemotherapy (HEC) is associated with a 70% risk of CINV, and moderately emetogenic chemotherapy (MEC) with a 30% to 90% risk.
- CINV, particularly in the delayed phase (24-120 h) following chemotherapy, can be a significant problem.

**APF530: BIOCHRONOMER® TECHNOLOGY**  
- APF530 is a novel extended-release formulation of 2% granisetron and triazolopyrimidine polyether polymer (TPE-POP), known as Biochronomer® (Figure 1).  
- On injection into the subcutaneous (SC) tissue, the polymer undergoes degradations by controlled hydrolysis, resulting in slow, sustained release of granisetron for 5 days (>120 h).
- One characteristic of Biochronomer technology is that the polymer remains in SC tissue while the drug is slowly released over time, thus being able to inhibit nociceptor reactions (ISRs), including nodules, which eventually resolve.

**RESULTS**  
- **Patients**  
  - The majority of patients were female and had an Eastern Cooperative Oncology Group performance status of 0 (Eastern Cooperative Oncology Group 2010; 21[suppl 5]:v232-v243).

**METHODS**  
- **The phase 3 MASC trial compared APF530 versus ondansetron, each in a gold-standard-recommended 3-drug regimen of a 5-hydroxytryptamine 3 (5HT3) receptor antagonist (RA), dexamethasone (D), and ondansetron (O).**
- **Patients** were stratified by planned use of cisplatin-based regimens and cytophologically confirmed malignancy, scheduled to receive chemotherapy.  
- **RESULTS**  
  - 902 patients were randomized to receive APF530 or ondansetron (Table 1).
  - TEAEs causing study discontinuation were evaluated, reported by type and severity, serious TEAEs, and treatment-emergent adverse events (TEAEs), with a focus on injection-site reactions (ISRs) including nodules, which eventually resolve.

**CONCLUSIONS**  
- **In the first US 3-drug versus 3-drug phase 3 efficacy trial for CINV prevention, APF530 versus ondansetron provided superior OR in the delayed phase following HEC.**
- **The APF530 regimen was generally well tolerated.**
- **Majority of ISRs were mild to moderate and resolved by study end.**
- **There were no new or unexpected safety findings.**
  - In our previous experience, APF530 administration in the abdomen or upper arm resulted in the preferred site and injection procedure.

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**REFERENCES**