Aponvie™ (aprepitant) – New drug approval

- On September 16, 2022, Heron Therapeutics announced the FDA approval of Aponvie (aprepitant) injectable emulsion, for the prevention of postoperative nausea and vomiting (PONV) in adults.
    - Aponvie has not been studied for the treatment of established nausea and vomiting.
- A different aprepitant injectable emulsion is available under the brand name Cinvanti® and approved in adults for the prevention of chemotherapy-induced nausea and vomiting.
- An oral formulation of aprepitant is available generically as a capsule as well as a branded oral suspension (Emend®).
    - The oral suspension and capsules are approved for prevention of chemotherapy-induced nausea and vomiting in patients 6 months of age and older and patients 12 years of age and older, respectively.
    - Generic versions of aprepitant capsules are also approved for the prevention of PONV in adults.
- The safety and efficacy of Aponvie have been established based on adequate and well-controlled studies of a single-dose of oral aprepitant in adults.
- Aponvie is contraindicated in patients:
    - With a history of hypersensitivity to aprepitant or any component of the product
    - Taking pimozide.
- Warnings and precautions for Aponvie include hypersensitivity reactions, clinically significant CYP3A4 drug interactions, decrease in International Normalized Ratio (INR) with concomitant warfarin, and risk of reduced efficacy of hormonal contraceptives.
- The most common adverse reactions (≥ 3%) with single-dose Aponvie use were constipation, fatigue, and headache. The most common adverse reactions (≥ 3%) with single-dose oral aprepitant use were constipation and hypotension.
- The recommended dose in adults of Aponvie is 32 mg administered as a 30 second intravenous injection prior to induction of anesthesia.
- Heron Therapeutics' launch plans for Aponvie are pending. Aponvie will be available as a 32 mg /4.4 mL single-dose vial.