Focinvez™ (fosaprepitant) – New drug approval

- On August 22, 2023, the FDA approved Spes Pharmaceuticals' Focinvez (fosaprepitant) injection, in combination with other antiemetic agents, in adults and pediatric patients 6 months of age and older for the prevention of:
  - Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin
  - Delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
- Focinvez has not been studied for the treatment of established nausea and vomiting.
- Fosaprepitant injection is also approved under the brand name Emend® for the same indications as Focinvez. Generic alternatives are available for Emend.
- The safety and efficacy of Focinvez have been established based on adequate and well-controlled adult studies of another intravenous (IV) formulation of fosaprepitant for the prevention and treatment of chemotherapy induced nausea and vomiting.
- Focinvez is contraindicated in patients with known hypersensitivity to any component of the drug and with concurrent use of pimozide.
- Warnings and precautions for Focinvez include clinically significant CYP3A4 drug interactions; hypersensitivity reactions; infusion site reactions; decrease in International Normalized Ratio (INR) with concomitant warfarin; and risk of reduced efficacy of hormonal contraceptives.
- The most common adverse reactions (≥ 2%) with Focinvez use in adults were fatigue, diarrhea, neutropenia, asthenia, anemia, peripheral neuropathy, leukopenia, dyspepsia, urinary tract infection, and pain in extremity. The adverse reactions in pediatric patients are similar to adults.
- Focinvez is administered via IV infusion. Refer to the drug label for complete dosing and administration recommendations.
- Spes Pharmaceuticals' launch plans for Focinvez are pending. Focinvez will be available as a 150 mg/50 mL single-dose vial.