Varubi® (rolapitant) injectable emulsion – New formulation approval

- On October 25, 2017, Tesaro announced the FDA approval of Varubi (rolapitant) injectable emulsion indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.
    - Varubi is the first intravenously (IV) administered neurokinin-1 (NK-1) receptor antagonist approved by the FDA that does not contain polysorbate 80.
    - Varubi is also available as a tablet.
- Varubi is a selective and competitive antagonist of human substance P/NK-1 receptors, which play an important role in the delayed phase of chemotherapy-induced nausea and vomiting.
- There are no clinical studies with the IV formulation of Varubi; however, results from a bioequivalence trial demonstrated comparability of the IV and oral formulations of Varubi.
- Results from three phase 3 trials of Varubi oral tablets demonstrated a significant reduction in episodes of vomiting or use of rescue medication during the 25- to 120-hour period following administration of highly emetogenic and moderately emetogenic chemotherapy regimens.
- Varubi is contraindicated in patients taking CYP2D6 substrates with a narrow therapeutic index, such as thioridazine and pimozide. Varubi can significantly increase the plasma concentrations of thioridazine and pimozide, which may result in QT prolongation and Torsades de Pointes.
- The most common adverse reactions (≥ 5%) with Varubi use:
    - Cisplatin based highly emetogenic chemotherapy: neutropenia and hiccups.
    - Moderately emetogenic chemotherapy and combinations of anthracycline and cyclophosphamide: decreased appetite, neutropenia and dizziness.
- The recommended dose of Varubi injectable emulsion is 166.5 mg administered by IV infusion over 30 minutes.
    - Varubi is administered in combination with a 5-HT_3 receptor antagonist and dexamethasone.
    - Refer to the Varubi drug label for specific dexamethasone dosing instructions.
    - Refer to the drug label for the co-administered 5-HT_3 receptor antagonist for appropriate dosing information.
    - Varubi is administered prior to the initiation of each chemotherapy cycle, but at no less than 2 week intervals.
- Tesaro plans to launch Varubi injectable emulsion in November 2017. Varubi will be available as a single dose vial containing 166.5 mg/92.5 mL (1.8 mg/mL) of rolapitant.