Rezenopy (naloxone) – New drug approval

- On April 19, 2024, the FDA approved Summit Biosciences' Rezenopy (naloxone) nasal spray, for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adult and pediatric patients.
    - Rezenopy nasal spray is intended for immediate administration as emergency therapy in settings where opioids may be present.
    - Rezenopy nasal spray is not a substitute for emergency medical care.
- Other formulations of naloxone are available as a nasal spray and injection for opioid overdose. This includes over-the-counter (OTC) formulations (eg, Narcan®).
- Warnings and precautions for Rezenopy include risk of recurrent respiratory and central nervous system depression, risk of limited efficacy with partial agonists or mixed agonist/antagonists, and precipitation of severe opioid withdrawal.
- The most common adverse reactions with Rezenopy use were abdominal pain upper, nasopharyngitis, and dysgeusia.
- The recommended initial dose of Rezenopy in adults and pediatric patients is one spray delivered by intranasal administration. Rezenopy should be administered as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death.
    - Emergency medical assistance should be sought as soon as possible after administering the first dose of Rezenopy.
    - The requirement for repeat doses of Rezenopy nasal spray depends upon the amount, type, and route of administration of the opioid being antagonized.
    - Refer to the drug label for complete dosing and administration instructions.
- Summit Biosciences' launch plans for Rezenopy are pending. Rezenopy will be available as a 10 mg nasal spray.