Opvee® (nalmefene) – New drug approval

- On May 23, 2023, Indivior announced the FDA approval of Opvee (nalmefene), for the emergency treatment of known or suspected overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression.
    - Opvee is intended for immediate administration as emergency therapy in settings where opioids may be present.
    - Opvee is not a substitute for emergency medical care.
- Opvee is an opioid receptor antagonist, which works quickly by blocking the brain opioid receptors.
    - In a clinical model of opioid-induced respiratory depression in opioid-experienced, non-dependent subjects, Opvee had an onset of action of 2.5 to 5 minutes and fully reversed respiratory depression as early as 5 minutes after Opvee administration.
- Warnings and precautions for Opvee include risk of recurrent respiratory and central nervous system depression; risk of limited efficacy with partial agonists or mixed agonist/antagonists; precipitation of severe opioid withdrawal; and risk of opioid overdose from attempts to overcome the blockade.
- The most common adverse reactions (≥ 2%) with Opvee use were nasal discomfort, headache, nausea, dizziness, hot flush, vomiting, anxiety, fatigue, nasal congestion, throat irritation, rhinalgia, decreased appetite, dysgeusia, erythema, and hyperhidrosis.
- The recommended initial dose of Opvee nasal spray in adults and pediatric patients aged 12 years and older is one spray delivered by intranasal administration, which delivers 2.7 mg of nalmefene.
    - Refer to the Opvee drug label for complete dosing and administration recommendations, including for repeat dosing.
- Indivior plans to launch Opvee in fourth quarter 2023. Opvee will be available as a nasal spray that delivers 2.7 mg of nalmefene (equivalent to 3 mg of nalmefene hydrochloride) in 0.1 mL.