Zimhi™ (naloxone) – New drug approval

- On October 18, 2021, Adamis Pharmaceuticals announced the FDA approval of Zimhi (naloxone), in adults and pediatric patients, for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
    - Zimhi is intended for immediate administration as emergency therapy in settings where opioids may be present.
    - Zimhi is not a substitute for emergency medical care.
- Zimhi is a high-dose formulation of naloxone injection (5 mg/0.5 mL). Naloxone is an opioid antagonist.
    - Other dosages of naloxone are currently available for opioid overdose in both intranasal and injection formulations.
- Warnings and precautions for Zimhi 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 Zimhi use were nausea, dizziness, lightheadedness, and elevated bilirubin.
- Zimhi is administered initially as a single-dose injection (5 mg naloxone) to adult or pediatric patients intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary, and seek emergency medical assistance. Zimhi should be administered as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death.
    - In pediatric patients under the age of one year, the caregiver should pinch the thigh muscle while administering Zimhi. The administration site should be carefully observed for signs of infection following resolution of the opioid emergency.
    - Refer to the Zimhi drug label for instructions on repeat dosing.
- Adamis Pharmaceuticals plans to launch Zimhi in the first quarter of 2021. Zimhi will be available as a 5 mg/0.5 mL solution in a single-dose prefilled syringe.