Kedrab™ (rabies immune globulin [human]) – New drug approval

- On August 25, 2017, Kedrion Biopharma and Kamada announced the FDA approval of Kedrab (rabies immune globulin [human]), indicated for passive, transient post-exposure prophylaxis of rabies infection, when given immediately after contact with a rabid or possibly rabid animal. Kedrab should be administered concurrently with a full course of rabies vaccine.
    - Do not administer additional (repeat) doses of Kedrab once vaccine treatment has been initiated, since this may interfere with the immune response to the rabies vaccine.
    - Do not administer Kedrab to persons with a history of a complete pre-exposure or post-exposure rabies vaccination and confirmed adequate rabies antibody titer.
- Rabies is a life-threatening condition that impacts approximately 40,000 people in the U.S. each year.
- The efficacy of Kedrab was demonstrated in a study of 118 healthy adults. Patients were randomized to Kedrab + rabies vaccine or a comparator human rabies immunoglobulin (HRIG) + rabies vaccine. The efficacy variable was rabies virus neutralizing antibody (RVNA) titer at day 14.
    - Efficacy (RVNA titer ≥ 0.5 IU/mL) was demonstrated in 98.2% of the Kedrab group and 100% of the comparator HRIG group.
- Warnings and precautions of Kedrab include previous rabies vaccination, anaphylactic shock, hypersensitivity, thrombosis, hemolysis, live attenuated virus vaccines, interference with serologic testing, and transmissible infectious agents.
- The most common adverse reactions with Kedrab use were injection site pain, headache, muscle pain, and upper respiratory tract infection.
- The recommended dosage of Kedrab is 20 IU/kg body weight intramuscularly, given at the time of the first vaccine dose.
    - Kedrab should not be mixed with the rabies vaccine or administered in the same syringe with the rabies vaccine.
    - Kedrab should not be administered into the same anatomical site(s) as rabies vaccine.
    - As much of the dose as possible of Kedrab should be infiltrated into and around any detectable bite wounds.
    - Consult the Kedrab drug label for further administration details.
- Kedrion Biopharma and Kamada plan to launch Kedrab in early 2018. Kedrab will be available as single-use vials containing 2 mL or 10 mL of ready-to-use solution with a potency of 150 IU/mL