U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

July 13, 2018

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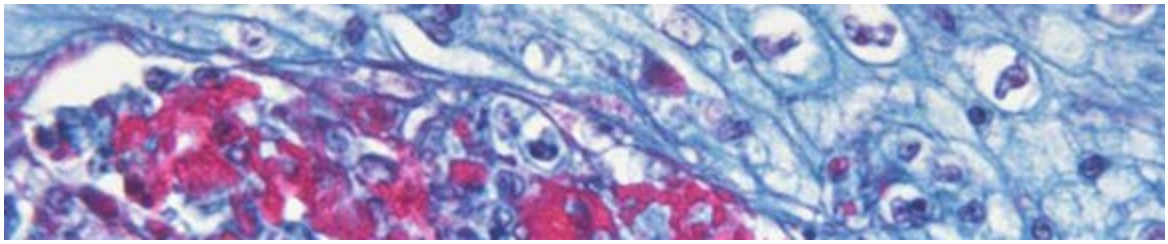

FDA approves the first drug with an indication for treatment of smallpox

July 13, 2018: FDA today approved TPOXX (tecovirimat), the first drug with an indication for treatment of smallpox. Though the World Health Organization declared smallpox, a contagious and sometimes fatal infectious disease, eradicated in 1980, there have been longstanding concerns that smallpox could be used as a bioweapon.

“To address the risk of bioterrorism, Congress has taken steps to enable the development and approval of countermeasures to thwart pathogens that could be employed as weapons. Today’s approval provides an important milestone in these efforts. This new treatment affords us an additional option should smallpox ever be used as a bioweapon,” said FDA Commissioner Scott Gottlieb, M.D. "This is the first product to be awarded a Material Threat Medical Countermeasure priority review voucher. Today’s action reflects the FDA’s commitment to ensuring that the U.S. is prepared for any public health emergency with timely, safe and effective medical products.”

TPOXX was developed in conjunction with the U.S. Department of Health and Human Services’ Biomedical Advanced Research and Development Authority (BARDA).

Read the full statement

Related links:

- **Smallpox preparedness and response updates from FDA (new web page!)**
- Material threat medical countermeasure priority review voucher program
- Draft Guidance for Industry: Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention (PDF, 120 KB, issued July 10, 2018) - FDA is accepting comments on this draft guidance until **September 10, 2018**.
- Smallpox information from CDC (includes information for clinicians, laboratory personnel, public health planners, and vaccinators)

Image: This photomicrograph demonstrates some of the histopathologic changes in a human skin tissue sample infected with the smallpox (Variola) virus. (Credit: CDC)

FDA approves chemical nerve agent treatment

On July 9, 2018, FDA approved the 2 mg Atropine Auto-Injector manufactured by Rafa Laboratories, Ltd., for the treatment of poisoning by susceptible organophosphorous nerve agents having cholinesterase activity as well as organophosphorous or carbamate insecticides in adults and pediatric patients weighing over 90 lbs [41 kg] (generally over 10 years of age). Atropine is a medicine, used as initial treatment, intended to reduce or block the effects of nerve agent or certain insecticide poisonings.

Related links:

- Approval letter (PDF, 49 KB)
- Product label (PDF, 482 KB)
- Nerve Agents - preparedness and response information from CDC

This is a special news alert. Scheduled MCMi email updates will return in late July.

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