March 28, 2016

**Anthim Approved for Inhalation Anthrax**

Anthim® (obiltoxaximab) is a monoclonal antibody that deactivates anthrax toxins that was approved by the U.S. Food and Drug Administration (FDA) on March 18, 2016. It will be used along with antibacterial drugs to treat inhalation anthrax. Anthim also was approved to prevent inhalation anthrax when other preventive measures are not practical. Anthim was developed by Elusys Therapeutics with funding from the U.S. Department of Defense (DoD), U.S. Department of Health and Human Services’ Biomedical Advanced Research and Development Authority (BARDA) and the National Institutes of Health (NIH). It is being added to the Strategic National Stockpile of drugs and medical supplies needed in a potential widespread emergency. Although its safety was tested in humans, effectiveness studies were carried out only with laboratory animals because infecting humans with anthrax is unethical.

A boxed warning on the labeling cautions about the possibility that Anthim may cause anaphylaxis (severe allergic reactions). After a dose of diphenhydramine, Anthim will be given as one intravenous (IV) infusion over 90 minutes. It should be given in a facility where the patient can be watched for signs of anaphylaxis and the staff is prepared to handle any potential adverse reactions. Dosing for Anthim is based on total body weight, with adults receiving 16 mg per kilogram (kg) of body weight and children needing higher amounts per kg. It will be dispensed in single-use 6 mL vials each containing 600 mg of Anthim. Prescribing information is available at: [http://www.anthim.com/download/pdf/ANTHIM-prescribing-information.pdf](http://www.anthim.com/download/pdf/ANTHIM-prescribing-information.pdf)

**Generic Launched for Voltaren Gel**

After FDA approval on March 18, 2016, Amneal Pharmaceuticals launched diclofenac gel 1%, the first generic for Voltaren® Gel (Endo Pharmaceuticals). A topical non-steroidal anti-inflammatory drug (NSAID), diclofenac gel is applied to the skin to treat osteoarthritis in affected joints. Diclofenac gel will be dispensed with a card that measures doses into two gram units (to be used for finger, hand, wrist and elbow joints) or 4 gram units (for foot, ankle and knee joints). It is indicated for use four times a day with total daily dosage of no more than 32 grams. All NSAIDs have a boxed warning that using them may raise the risk of heart attacks, strokes and gastrointestinal (GI) problems, such as stomach bleeding and ulcers. Diclofenac gel is available in 100 gram tubes. For the 12-month period that ended on January 31, 2016, IMS Health estimated that Voltaren Gel had sales of $413 million in the United States.

**MedWatch Update**

**Opioids**

FDA issued a Drug Safety Communication on March 22, 2016, for drugs in the opioid class. The labels for all immediate-release (IR) opioids now have to include a boxed warning about the potentials for abuse, addiction, misuse, overdosing and death that are associated with using them. A caution about neonatal withdrawal syndrome for babies born to women who used opioids while pregnant is required, as well.

Usually prescribed to be taken once every four to six hours, IR opioids should be used only for severe pain that is not controlled by non-opioids.
FDA also noted that all opioids – both immediate- and extended-release forms – may have adverse reactions when used with other drugs and that they may interfere with some normal body functions. Manufacturers of all opioids will add information to opioid labeling about three additional possible risks. First, opioids may interact with a large number of antidepressants, anti-nausea drugs, migraine medications or other prescription and over-the-counter (OTC) drugs. Potentially, an interaction could cause serotonin syndrome, a rare condition that involves an excess of the neurotransmitter, serotonin, in the central nervous system (CNS). Symptoms may include confusion, coma, fever, hallucinations and muscle twitches. Secondly, opioids may block the production of a hormone, cortisol, by the adrenal glands. Although cortisol suppression is very uncommon, it can be very serious. However, its symptoms are general and they usually develop slowly. They are not always recognized until the patient experiences a crisis, such as unconsciousness, extremely low blood pressure or severe abdominal or back pain. Finally, FDA warns that using opioids for long periods can inhibit sex hormones. Individuals who use opioids chronically may lose interest in having sex. Amenorrhea (lack of menstruation), erectile dysfunction, impotence or infertility also may result. For lists of generic and brand name opioids and some of the other drugs that could interact with them, details on the symptoms of cortisol and sex hormone deficiencies and more information on the warnings; the complete FDA communication is at: http://www.fda.gov/Drugs/DrugSafety/ucm489676.htm.