Cetylev™ (acetylcysteine) – New Drug Approval

- On February 9, 2016, Arbor Pharmaceuticals announced the FDA approval of Cetylev (acetylcysteine) effervescent tablets for oral solution, to prevent or lessen hepatic injury after ingestion of a potentially hepatotoxic quantity of acetaminophen in patients with acute ingestion or from repeated supratherapeutic ingestion.

- Acetylcysteine is also available generically as a solution for inhalation, indicated as adjuvant therapy for patients with abnormal, viscid, or inspissated mucous secretions in a variety of conditions and as a solution for intravenous administration, which shares the same indication as Cetylev.

- Acetaminophen overdose accounted for 108 deaths in 2014 from a reported 73,347 exposures according to the American Association of Poison Control Centers.

- Warnings and precautions of Cetylev include hypersensitivity reactions and risk of upper gastrointestinal hemorrhage.

- The most common adverse events with Cetylev use were nausea and vomiting, other gastrointestinal symptoms, and rash with or without fever.

- The recommended dosage of Cetylev for adult and pediatric patients is an oral loading dose of 140 mg/kg. The maintenance dosage is 70 mg/kg given orally and repeated every 4 hours for a total of 17 doses.

  — Detailed information for pre-treatment assessment and acetaminophen concentration monitoring is found in the product labeling. This information should be used to guide when to give the loading dose and whether to continue maintenance dosing.

- Cetylev effervescent tablets are prepared by dissolving the appropriate number of tablets in a specified volume of water as instructed in the drug label. It is for oral administration only and not to be administered via nebulization or intratracheal instillation.

- Arbor Pharmaceuticals’ launch plans for Cetylev are pending. Cetylev will be available as 500 mg and 2.5 gram effervescent tablets.