New drug information

- **Arymo™ ER (morphine, extended release):** The Food and Drug administration (FDA) approved Egalet’s Arymo ER for the management of pain severe enough to require daily, around-the-clock, long-term treatment for which alternative treatment options are inadequate. Arymo ER is available as a 15 mg, 30 mg, and 60 mg tablet. The FDA said the drug is formulated to give it physicochemical properties expected to make abuse by injection difficult.1

- **Vantrela™ ER (hydrocodone bitartrate, extended release):** The FDA approved Teva’s Vantrela ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatments are inadequate. Vantrela ER is available as a 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg extended-release tablet. Vantrela ER incorporates abuse-deterrent technology that is expected to resist drug extraction via oral, intranasal, and intravenous routes when the tablets are manipulated.2

- **Trulance™ (plecanatide):** The FDA approved Synergy’s Trulance, taken orally once daily, for the treatment of adults with chronic idiopathic constipation (CIC). Trulance will compete with Amitiza® (lubiprostone) and Linzess® (linaclootide) in the CIC market. Trulance will be available later this quarter.

- **Rhofade (oxymetazoline 1% cream):** The FDA approved Allergan’s Rhofade™ for the once daily application of rosacea (persistent facial redness). Rhofade will be available starting in May 2017.

New generics

- **Emend® (aprepitant):** Sandoz has launched a generic version of Merck’s Emend capsules for the treatment of chemotherapy induced nausea and vomiting and prevention of postoperative nausea and vomiting. Whether Sandoz has exclusivity has not been determined, but no other companies are launching a generic at this time. According to IMS, Emend had approximately $553 million in U.S.

- **Concerta® (methylphenidate extended-release [XR]):** Mylan launched the first true generic version of Janssen’s Concerta for the treatment of attention deficit hyperactivity disorder (ADHD). Before this approval, Actavis/Teva had an authorized generic version of Concerta on the market. Previous to Mylan’s launch, two other manufacturers had launched their generics of Concerta, but the FDA removed their interchangeability designation in 2014 because they failed to demonstrate that their products provide the same therapeutic effect as (are bioequivalent to) the brand-name drug they reference. According to IMS, Concerta had approximately $1.59 billion in annual U.S. sales for all strengths.

- **Azilect® (rasagiline):** Alvogen has launched Teva Neuroscience’s Azilect for the treatment of Parkinson’s disease. Prior to this generic, Teva had launched an authorized generic for this drug. No exclusivity remains. According to IMS, Azilect had approximately $108 million in annual U.S. sales.
New generics (continued)

- **Focalin XR® (dexmethylphenidate):** Par has launched Novartis’ Focalin XR capsules for the treatment of ADHD in patients aged 6 years and older. After the 180 day exclusivity period, four manufacturers are preparing to launch their generics. According to IMS, the 25 mg capsule had $66 million and the 35 mg capsule had $14 million in annual U.S. sales.

- **Aggrenox® (aspirin/dipyridamole):** Amneal Pharmaceuticals launched the first true generic for Boehringer Ingelheim’s Aggrenox. Two authorized generics have been available prior to Amneal’s approval. No exclusivity remains. Aggrenox had $457 million in U.S. annual sales according to IMS.

- **Kaletra® (lopinavir/ritonavir):** Lannett has launched the first generic for AbbVie’s Kaletra oral solution for the treatment of HIV infection in adults and pediatric patients (14 days and older) in combination with other agents. No exclusivity remains.

January news

- “Cempra, a clinical-stage pharmaceutical company focused on developing antibiotics to meet critical medical needs in the treatment of bacterial infectious diseases, announced that the company has received a Complete Response Letter (CRL) from the FDA relating to the company’s new drug applications (NDAs) for oral and intravenous solithromycin for the treatment of community-acquired bacterial pneumonia (CABP) in adults.”

- “Tesaro, an oncology-focused biopharmaceutical company, announced that the FDA has issued a CRL regarding the rolapitant IV NDA for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy. The FDA requested additional information regarding the in vitro method utilized to demonstrate comparability of drug product produced at the two proposed commercial manufacturers for rolapitant IV that were included in the NDA. Tesaro is working expeditiously to provide the requested information.”

References


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