New drug information

● **Prevymis™ (letermovir):** Merck Sharp & Dohme received U.S. Food and Drug Administration (FDA) approval for Prevymis for the prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). Prevymis is available as tablets or for intravenous administration. Merck expects to launch Prevymis in December 2017.¹

● **Cinvanti™ (aprepitant):** The FDA approved Heron Therapeutics’ Cinvanti, in combination with other antiemetic agents for the prevention of:

  → Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy; and

  → Nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

  Cinvanti and Merck’s Emend® have the same active ingredient, aprepitant; but unlike Emend, Cinvanti doesn’t contain polysorbate 80. Polysorbate 80 can cause allergic reactions and infusion-site reactions. Cinvanti is only available as an IV product; Emend is available in IV and oral capsule formulations.

● **Abilify® Mycite™:** The FDA approved Otsuka’s Abilify Mycite for the treatment of adults with schizophrenia, bipolar I disorder, and as an adjunctive treatment of adults with major depressive disorder (MDD). Abilify MyCite, although not approved for irritability associated with autistic disorder or Tourette’s disorder, is similar to Abilify with the addition of an embedded Ingestible Event Marker (IEM) sensor intended to track drug ingestion. The Abilify MyCite system is composed of:

  → The Abilify tablet embedded with an IEM sensor

  → The MyCite Patch, a wearable sensor that detects the signal from the sensor after ingestion and transmits data to a smartphone

  → The MyCite smartphone application used to display information for the patient

  → A web-based portal for health care professionals and caregivers

  The ability of Abilify MyCite to improve patient compliance or modify Abilify dosage has not been established.

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New generics

- **Aczone 5% (dapsone gel, 5%)**: Taro launched the first true generic for Allergan’s Aczone 5% for the topical treatment of acne vulgaris. Another generic product launch is not anticipated until 2018–2019. According to IMS, all strengths of Aczone had approximately $61.2 million in U.S. annual sales.

- **Tamiflu (oseltamivir oral suspension)**: Alvogen and Zydus launched their generic versions of Genentech’s Tamiflu suspension for the treatment and prophylaxis of influenza A and B. Lupin is awaiting FDA approval for their generic version of Tamiflu suspension. According to IMS, Tamiflu suspension had approximately $312 million in annual U.S. sales.

- **Coreg CR (carvedilol ER 24 hr capsules)**: Sun launched their generic version of GlaxoSmithKline’s Coreg CR for the treatment of heart failure, left ventricular dysfunction following myocardial infarction, and hypertension. Multiple other generic manufacturers are awaiting FDA approval but may have to wait to launch until May 2018, pending an FDA decision on Sun’s 180-day exclusivity eligibility. According to IMS, Coreg CR had approximately $208 million in U.S. annual sales.

References


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