New drug information

- **Ezallor™ (rosuvastatin):** The Food and Drug Administration (FDA) approved Sun Pharma’s Ezallor capsules for the treatment of adult patients with hypertriglyceridemia or primary dysbetalipoproteinemia as an adjunct to diet and for the adult patients with homozygous familial hypercholesterolemia. Rosuvastatin is also available as AstraZeneca’s Crestor® tablets and its generics. Crestor is also approved for patients aged 7 to 17. Sun Pharmaceuticals’ launch plans for Ezallor are pending.

- **Brixadi™ (buprenorphine):** Braeburn Pharmaceuticals received FDA tentative approval for Brixadi for the treatment of moderate to severe opioid use disorder (OUD) in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. Brixadi is an extended-release medication. It’s available in pre-filled syringes and administered subcutaneously by the health care provider in a health care setting on a weekly or monthly basis as part of a complete treatment program that includes counseling and psychosocial support. With its tentative approval, the FDA concluded that Brixadi met all required quality, safety and efficacy standards necessary for approval, but is not eligible for marketing in the United States due to exclusivity considerations of Indivior’s Sublocade®. The exclusivity period for Sublocade is set to expire in late 2020. Sublocade administration can be given following a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days. Brixadi administration can occur following a single dose of a transmucosal buprenorphine.

- **Elepsia XR™ (levetiracetam) extended-release:** The FDA approved Sun Pharma’s Elepsia XR as an adjunctive therapy for the treatment of partial-onset seizures in patients 12 years of age and older. Levetiracetam extended-release is also available as UCB’s Keppra XR® and its generics. Elepsia XR was originally approved in March 2015, but due to manufacturing issues, the FDA issued a Complete Response Letter (CRL) and revoked the approval in September 2015. Sun Pharma’s current launch plans are pending.
**New drug information (continued)**

- **Licart® (diclofenac epolamine):** IBSA Institut Biochimique received FDA approval for Licart for the topical treatment of acute pain due to minor strains, sprains, and contusions. Licart is a topical system nonsteroidal anti-inflammatory drug (NSAID) that is applied to the most painful area once daily. Pfizer’s Flector® patch (diclofenac epolamine) is available for the same indication but dosed twice daily. IBSA’s launch plans are pending.

**Generic drug information**

- **Canasa® (mesalamine) rectal suppository:** Mylan launched the first true generic of Allergan’s Canasa for the treatment of mildly to moderately active ulcerative proctitis. Greenstone launched an authorized generic for Canasa. Mylan has 180-day exclusivity. Several other generics are expected to launch after the expiration of Mylan’s exclusivity in June 2019. Canasa generated $263 million in U.S. annual sales in 2017.

- **Elidel® (pimecrolimus cream 1%):** Actavis Pharma launched the first true generic for Valeant’s Elidel for second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable. Oceanside launched an authorized generic version of Elidel. Elidel is no longer protected by any patents or regulatory exclusivities; however, no other manufacturers have FDA-approved generics. Elidel had annual sales of approximately $218.4 million in the United States.

**References**


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