New drug information

- **Tosymra™ (sumatriptan) nasal spray:** The U.S. Food and Drug Administration (FDA) approved Promius Pharma and Dr. Reddy's Laboratories' Tosymra for the acute treatment of migraine with or without aura in adults. Tosymra is available in a 10 mg nasal spray; GSK's Imitrex® (sumatriptan) nasal spray and its generics are available in 5 mg and 20 mg strengths. Tosymra achieves blood levels similar to a sumatriptan subcutaneous injection of 4 mg.¹ Launch plans and pricing are pending.

- **Gloperba™ (colchicine):** Romeg Therapeutics was granted FDA approval for Gloperba for the prophylaxis of gout flares in adults. This is the first formulation of colchicine available in an oral solution. Colchicine is available generically in tablets and capsules. Romeg anticipates launching Gloperba in the second half of 2019.

- **Evekeo ODT™ (amphetamine sulfate) orally disintegrating tablets:** The FDA approved Arbor Pharmaceuticals Evekeo® ODT for the treatment of ADHD in 5 mg, 10 mg, 15 mg and 20 mg strengths. Arbor also manufactures Evekeo 5 mg and 10 mg immediate release tablets which are FDA approved for the treatment of ADHD as well as narcolepsy and exogenous obesity; generics are also available for the immediate-release tablets. Launch plans and pricing are pending.

- **Egaten™ (triclabendazole):** Novartis received FDA approval for Egaten for the treatment of fascioliasis in patients 6 years of age and older. Prior to this approval, triclabendazole was being distributed in the United States through a special arrangement with the FDA and Novartis on an individual patient basis.

- **Jeuveau™ (prabotulinumtoxinA-xvfs):** The FDA approved Evolus’ Jeuveau for the temporary improvement in the appearance of moderate to severe glabellar (frown) lines in adult patients administered via intramuscular injection. Evolus expects to launch in spring 2019 at a 20-25% lower price than Allergan's Botox® (onabotulinumtoxinA).²

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Generic drug information

- **Sabril® (vigabatrin) tablets**: Actavis Pharma launched the first generic for Lundbeck’s Sabril tablets for the treatment of refractory complex partial seizures as adjunctive therapy in patients ≥10 years of age who have responded inadequately to several alternative treatments; or as monotherapy for infantile spasms in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss. Prior to the generic tablets launch, Sabril powder for oral solution was available generically. Sabril tablets generated $181 million in annual U.S. sales in 2017.

- **Fareston® (toremifene)**: Rising Pharmaceuticals launched the first generic for Kyowa Kirin’s Fareston for the treatment of metastatic breast cancer in postmenopausal women with estrogen-receptor positive or unknown tumors. No exclusivities remain.

- **Rapamune® (sirolimus) oral solution**: Vistapharm launched the first generic solution for Pfizer’s Rapamune for the prophylaxis of organ rejection in patients aged 13 years or older receiving renal transplants. Prior to the generic oral solution launch, Rapamune tablets were available generically. Rapamune oral solution generated $29 million in annual U.S. sales in 2017.

- **Zovirax® (acyclovir) cream for topical use**: Perrigo Pharmaceuticals launched the first generic for Bausch Health’s Zovirax cream for the treatment of recurrent cold sores in patients aged 12 years of age and older. Zovirax ointment has been available generically since 2013. Zovirax cream generated $102 million in U.S. annual sales in 2017.

- **Solodyn® (minocycline HCl) extended release tablets 80 mg, 105 mg**: Ascend Laboratories launched the first generic for Bausch Health’s Solodyn for the treatment of inflammatory lesions of non-nodular moderate to severe acne in patients 12 years of age and older. Several other manufacturers are set to launch their 80 mg and 105 mg generics in February 2019. Other strengths are also available generically. Solodyn 80 mg and 105 mg tablets generated $164 million in U.S. annual sales in 2017.

- **Renagel® (sevelamer hydrochloride) tablets**: Glenmark Pharmaceuticals launched the first generic for Genzyme’s Renagel tablets for the control of serum phosphorus in patients with chronic kidney disease on dialysis. Winthrop launched an authorized generic of Renagel 800 mg tablets. Other manufacturers are awaiting FDA approval for their generic products. Renagel generated $186 million in U.S annual sales in 2017.

- **Advair Diskus® (fluticasone propionate and salmeterol inhalation powder), for oral inhalation**: Wixela™ Inhub™, the first true generic of GSK’s Advair Diskus, was launched by Mylan for the treatment of certain patients with asthma or chronic obstructive pulmonary disease (COPD). Prasco launched an authorized generic for Advair Diskus. Other manufacturers are not expected to launch their generic Advair Diskus products until 2020. Advair Diskus generated $4.2 billion in U.S. sales for the 12 months ending November 2018.

References


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