New drug information

- **Andexxa® [coagulation factor Xa (recombinant), inactivated-zhza]**: The Food and Drug Administration (FDA) approved Portola’s Andexxa, the first antidote indicated for patients treated with rivaroxaban and apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. Andexxa was approved under the FDA’s Accelerated Approval pathway; continued approval may be contingent upon post-marketing study results to demonstrate an improvement in hemostasis in patients.

- **Plenvu® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution)**: Salix and Norgine received FDA approval of Plenvu, an osmotic laxative for cleansing of the colon in preparation for colonoscopy in adults. Plenvu is the lowest, total-volume preparation bowel cleanser available in the U.S.¹

- **Lucemyra™ (lofexidine)**: The FDA approved US WorldMeds’ Lucemyra for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults. Patients who discontinue opioids endure withdrawal symptoms such as anxiety, nausea, vomiting, insomnia, muscle aches and more; Lucemyra is designed to fight these symptoms but may not completely prevent them. The dosage is three 0.18 mg tablets 4 times daily for up to 14 days. Lucemyra was not approved for opioid use disorder.

- **Lokelma™ (sodium zirconium cyclosilicate)**: AstraZeneca received FDA approval of Lokelma for the treatment of hyperkalemia in adults. Before approval, AstraZeneca had received two Complete Response Letters (CRLs) from the FDA because of manufacturing issues.² Lokelma will compete for market share with Relypha’s Veltassa® (patiromer), also indicated for the treatment of hyperkalemia.
New generics

- **Zavesca® (miglustat):** Amerigen Pharmaceuticals launched their generic version of Actelion Pharmaceuticals’ Zavesca for the treatment of adult patients with mild/moderate of type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option. No exclusivities remain.

- **Biltricide® (praziquantel):** Par Pharmaceuticals launched their generic version of Bayer Healthcare Pharma’s Biltricide for the treatment of infections due to all species of Schistosoma, infections due to liver fluke, and Clonorchis sinensis/Oipisthorchis viverrini.

- **Targadox® (doxycycline hyclate), 50 mg tablet:** JG Pharma launched the first generic of Journey Medical Corporation’s Targadox 50 mg tablet for the treatment of bacterial infections and certain gram-negative microorganisms. Other doxycycline hyclate tablets were available generically prior to this launch including doses of 20 mg, 75 mg, 100 mg, and 150 mg.

- **Welchol® (colesevelam hydrochloride) tablets, 625 mg:** Impax Generics has launched the first generic version of Sankyo’s Welchol tablets indicated as an adjunct to: diet and exercise to reduce cholesterol in adults with primary hyperlipidemia; adolescents aged 10 – 17 with heterozygous familial hypercholesterolemia; and improve glycemic control in adults with type 2 diabetes mellitus. It is unknown when the FDA will grant effective approval to other generic manufacturers of colesevelam. According to IQVIA, Welchol tablets had annual U.S. sales of approximately $519.9 million for the 12 months ending in March 2018.

References


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