Drug Pipeline Monthly Update

Critical updates in an ever changing environment

August 2017

New drug information

- **Lusduna® Nexvue™ (insulin glargine injection):** The U.S. Food and Drug Administration (FDA) granted tentative approval to Merck’s Lusduna Nexvue, a follow-on biologic basal insulin to Sanofi's Lantus, to improve glycemic control in patients with type 1 and 2 diabetes mellitus. Lusduna Nexvue has met all required regulatory standards for follow-on biologics of clinical and nonclinical safety, efficacy and quality, but is subject to an automatic stay due to a lawsuit from Sanofi claiming patent infringement. The initiation of Sanofi’s lawsuit in September 2016 automatically invoked a stay on final FDA approval for a period of up to 30 months, or in the event a court finds in favor of Merck, whichever comes sooner.

- **Qvar® RediHaler™ (beclomethasone dipropionate HFA) inhalation aerosol:** The FDA approved Teva's Qvar RediHaler, a breath-actuated inhaler for the maintenance treatment of asthma in patients 4 years of age and older. The Qvar RediHaler administers the same active drug ingredient found in Qvar (beclomethasone dipropionate HFA) with a different mode of delivery. The RediHaler delivers beclomethasone via a breath-actuated MDI, eliminating the need for hand-breath coordination during inhalation. It does not need to be shaken or primed and should not be used with a spacer or volume holding chamber. The launch is expected in 1Q2018.

- **Nikita™ (pitavastatin sodium):** Lupin received 505(b)(2) approval for Nikita tablets from the FDA. Nikita is an alternate salt product of Kowa Company Ltd’s Livalo (pitastatin calcium) tablets.

- **Duzallo™ (lesinurad/allopurinol):** Ironwood Pharmaceuticals announced that the FDA approved Duzallo for the once-daily treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of allopurinol alone. Duzallo combines Ironwood Pharmaceuticals/AstraZeneca’s Zurampic (lesinurad) and allopurinol together in one tablet, versus taking the two medications separately. Zurampic should not be used as monotherapy. Ironwood anticipates Duzallo to launch in the fourth quarter of 2017 at a price that may be comparable to Zurampic.³
**New generics**

- **Lialda® (mesaline delayed release [DR]):** Zydus Pharmaceuticals has launched the first generic for Shire’s Lialda for the induction of remission in patients with active, mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis. The FDA will only make a formal determination of Zydus’s eligibility for 180-day exclusivity if another manufacturer’s ANDA can be approved within 180 days after the Zydus launch. According to IMS, Lialda had approximately $714 million in sales over the past year.

- **Renvela® (sevelamer carbonate):** Aurobindo Pharma has launched the first generic for Genzyme’s Renvela tablets for the control of serum phosphorus in adults and children 6 years of age and older with chronic kidney disease on dialysis. It is unknown as to when the FDA will grant approval to additional manufacturer’s generic Renvela tablets.

- **Relpax® (eletriptan):** Teva, Greenstone, Mylan, and Zydus Pharmaceuticals have launched their generic versions of Pfizer’s Relpax for the acute treatment of migraine with or without aura in adults. According to IMS, Relpax had $371 million in sales over the past year.

- **Transderm-Scop® (scopolamine):** Perrigo Pharmaceuticals launched their generic version of Transderm-Scop (Sandoz, Baxter Healthcare, Glaxo Consumer Healthcare), a transdermal patch for the prevention of nausea and vomiting associated with motion sickness and for post-operative nausea and vomiting. According to IMS, Transderm-Scop had approximately $158 million in sales over the past year.

- **Epiduo® (adapalene/benzoyl peroxide):** Actavis launched the first generic for Galderma’s Epiduo gel for the topical treatment of acne vulgaris in patients 9 years of age and older. Multiple manufacturers are expected to launch their generic versions of Epiduo in January 2018. According to IMS, Epiduo had approximately $271 million in sales over the past year.

- **Effient® (prasugrel):** Mylan has launched the first generic of Eli Lilly/Daiichi Sankyo’s Effient to reduce the rate of thrombotic cardiovascular events in certain patients. Also, Prasco launched an authorized generic of Effient. According to IPD analytics, Effient had approximately $662 million in sales over the past year.

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**References**


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