Drug Pipeline Monthly Update

Critical updates in an ever changing environment

July 2017

New drug information

- **Mydayis™ (mixed salts of a single-entity amphetamine product) extended-release capsules, CII:** The Food and Drug Administration (FDA) approved Shire’s Mydayis for the once daily treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older. Pediatric patients 12 years and younger experienced higher plasma exposure than patients 13 years and older at the same dose and experienced higher rates of adverse reactions, mainly insomnia and decreased appetite.

- **Cotempla™ XR-ODT (methylphenidate extended-release orally disintegrating tablets), CII:** The FDA approved Neos Therapeutics’ Cotempla XR-ODT for the once daily treatment of ADHD in pediatric patients 6-17 years of age.

- **Bevyxxa™ (betrixaban):** The FDA approved Portola’s Bevyxxa for the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE. This is the first anticoagulant approved for extended-duration prophylaxis (35 to 42 days) of VTE in this patient group. Portola expects to launch Bevyxxa between August and November 2017.\(^1\)

New generics

- **Axiron (testosterone topical transdermal solution, 30 mg/1.5 mL actuation):** Perrigo and Prasco have launched the first generics of Lilly’s Axiron for replacement therapy in males for certain conditions associated with a deficiency or absence of endogenous testosterone. Additional manufacturers are set to launch their generic versions of Axiron in the second half of 2017. According to IMS, Axiron had approximately $254 million in sales over the past year.

- **Alkeran (melphalan tablet):** Alvogen launched the first generic for Apo Pharma’s Alkeran 2 mg tablets for the palliative treatment of multiple myeloma and for the palliation of non-resectable epithelial carcinoma of the ovary.

- **Vigamox (moxifloxacin ophthalmic solution 0.5%):** Apotex launched the first generic for Novartis’ Vigamox for the treatment of bacterial conjunctivitis. Lupin has also launched their generic product. Teva is expected to launch their generic version of Vigamox in July 2017. According to IMS, Vigamox had $267.9 million in annual sales last year.

While the information in this newsletter is from sources we believe to be reliable, we do not warrant that the information in this document is free from error. Use it only as a guide. Statements regarding drugs or manufacturers are not intended as promotion; those statements should not be used to make assumptions about formulary status. Each trademarked drug name is the property of its respective owner.
References


All brand names are property of their respective owners.