New drug information

- **Perseris™ (risperidone extended-release injectable suspension):** The US Food and Drug Administration (FDA) approved Indivior’s Perseris for the treatment of schizophrenia in adults. Perseris is a subcutaneous injection that is administered once-monthly by a healthcare professional. Indivior is reviewing appropriate launch timing and will provide a launch date no later than November 1, 2018.¹

- **Arakoda™ (tafenoquine):** Sixty Degrees Pharmaceuticals, in collaboration with the U.S. Army Medical Research and Material Command, was granted FDA approval of Arakoda for the prevention of malaria. Arakoda is a once weekly formulation for patients 18 years of age and older.

- **Annovera™ (segesterone acetate and ethinyl estradiol vaginal system):** The FDA approved the TherapeuticsMD, Inc’s Annovera, a contraceptive vaginal ring to prevent pregnancy for one year. Annovera is inserted into the vagina for 3 weeks followed by removal for one week. The schedule is repeated every 4 weeks for 1 year (thirteen 28-day menstrual cycles). Launch is anticipated in fourth quarter of 2019 or first quarter of 2020.²

- **Cequa™ (cyclosporine ophthalmic solution) 0.09%:** Sun Pharma received FDA approval for Cequa to increase tear production in patients with keratoconjunctivitis sicca (dry eye). Cequa is dosed twice daily and will be available as a single-use vial. Cequa will compete with Allergan’s Restasis® (cyclosporine ophthalmic emulsion 0.5%) and Shire’s Xiidra® (lifitegrast ophthalmic solution) 5% in the dry eye disease market; as well as, possible Restasis generic competition in 2018.

- **Jornay PM™ (methylphenidate hydrochloride) extended-release capsules:** Ironshores’ Jornay PM was approved by the FDA for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older. Jornay PM is the only stimulant medication that is dosed in the evening and has demonstrated improvement in ADHD symptoms in the morning and throughout the day. Launch is anticipated in the first half of 2019.³

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Generic drug information

- **Topicort® Topical Spray (desoximetasone, 0.25%)**: Lupin Pharmaceuticals launched the first generic version of Taro's Topicort Topical Spray for the treatment of plaque psoriasis in adults. Other generic manufactures are expected to launch their generic versions of Topicort Topical Spray in 2020. According to IMS Health, Topicort spray generated $18.7 million in US annual sales last year.

- **Eurax® Lotion (crotamiton)**: Marnel Pharmaceutical launched their generic version of Ranbaxy Laboratories’ Eurax Lotion for the treatment of scabies and pruritic skin.

- **Asacol® HD (mesalamine DR tab, 800 mg)**: Zydus Pharmaceuticals launched their generic version of Allergan's Asacol HD 800 mg tablet for the treatment of ulcerative colitis.

- **Dexpak® (dexamethasone tab therapy packs)**: Larken Laboratories, Inc launched their generic version of Valeant’s Dexpak for the treatment of arthritis, allergic reactions, blood/hormone/immune system disorders, certain skin and eye conditions, breathing problems, certain bowel disorders, and certain cancers.

- **Cosopt® PF (dorzolamide hydrochloride/timolol maleate opthalmic solution, 2%/0.5%)**: Aurobindo Pharma launched their generic version of Cosopt PF for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers.

- **Adcirca® (tadalafil tab)**: Mylan launched their generic version of Lilly’s Adcirca for the treatment of pulmonary arterial hypertension (PAH-WHO Group 1) to improve exercise ability. Mylan received 180-day exclusivity; in February 2019 multiple manufacturers anticipate launch of their generic versions of Adcirca. According to IMS Health, Adcirca generated $510 million in US annual sales last year.

References


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