Drug Pipeline Monthly Update

Critical updates in an ever changing environment

February 2018

New drug information

- **Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide):** The Food and Drug Administration (FDA) approved Gilead’s Biktarvy as a complete regimen (1 tablet taken once daily) for the treatment of HIV-1 infection in adults with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen for at least 3 months with no history of treatment failure and no known substitutions associated with resistance to the individual components. Gilead launched Biktarvy with a wholesale acquisition cost (WAC) of $2,945.65 for a 30-tablet bottle which is at parity to Gilead’s Genvoya® (elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide). ¹

- **Osmolex ER™ (amantadine extended-release tablets):** Osmotica Pharmaceutical received FDA approval for Osmolex ER for the treatment of Parkinson’s disease and drug-induced extrapyramidal symptoms. Osmolex ER is a taken once daily in the morning. It differs in indication from Adamas Pharmaceuticals’ Gocovri™ (amantadine extended-release capsules) which is FDA approved for the treatment of dyskinesia in Parkinson’s disease patients receiving levodopa-based therapy, with or without concomitant dopaminergic medicines.
New generics

- **Sustiva® (efavirenz) 600 mg**: Mylan has launched the first generic version of Bristol-Myers Squibb's Sustiva 600 mg tablets for the treatment of HIV-1 infection. Mylan has marketing exclusivity for 180 days after which multiple manufacturers will launch their generic versions. U.S. annual sales of Sustiva 600 mg tablets was approximately $113 million in the past year, according to IQVIA.

- **Syprine® (trientine)**: Actavis Pharma launched its generic version of Valeant’s Syprine for the treatment of patients with Wilson’s disease who are intolerant of penicillamine. Kadmon is waiting for approval of its generic Syprine product. No regulatory exclusivities or patent protections remain. According to IMS data, Syprine had $155 million in U.S. annual sales.

- **Locoid® Lotion (hydrocortisone butyrate)**: Teligent has launched the first generic version of Valeant’s Locoid Lotion for the treatment of mild to moderate atopic dermatitis. Teligent has 180 days of marketing exclusivity after which Lupin may launch its generic version of Locoid Lotion. According to IMS data, Locoid Lotion had approximately $17 million in sales over the past year.

- **Treximet® (sumatriptan/naproxen) 85 mg – 500 mg**: Aurobindo Pharma launched its generic version of Pernix’s Treximet 85 mg-500 mg tablets for the acute treatment of migraine with or without aura. Mylan is also eligible to launch its generic version of Treximet. Other manufacturers may launch their generic versions of Treximet in April 2018.

References

1. http://www.bioworld.com/content/gsk-seeks-spoil-gileads-party-biktarvy-hiv-0

All brand names are property of their respective owners.