Drug Pipeline Update

Drug Insights † April 2016

New drug information

- **BromSite™ (bromfenac 0.075%)**: The Food and Drug Administration (FDA) approved InSite Vision’s low dose topical bromfenac for the treatment of inflammation and pain associated with cataract surgery.

- **Luveris® (lutropin alpha for injection)**: The FDA withdrew the new drug application approval for EMD Serono’s Luveris, an injectable fertility treatment. Luveris was originally approved in 2004 under the accelerated approval pathway. EMD Serono requested the application be withdrawn as they did not conduct the required post-marketing trial to establish safety and efficacy.¹

New generics

- **Nasonex® (mometasone nasal spray)**: Apotex has launched its generic version of Merck’s Nasonex for the treatment of seasonal allergies. According to IMS Health, Nasonex had approximately $955 million in annual U.S. sales.

- **Enablex® (darifenacin 24 hr sustained-release tabs)**: The first generic of Actavis’ Enablex for adults with overactive bladder is now available.

- **Intermezzo® (zolpidem sublingual tablets)**: The first generic of Purdue Pharma’s Intermezzo for the treatment of insomnia has launched. Intermezzo had less than $10 million in annual U.S. sales.

- **Frova® (frovatriptan tab)**: Glenmark Pharmaceuticals has launched their generic version of Endo’s Frova for the treatment of migraines. According to IMS Health, Frova had approximately $88 million in annual U.S. sales.

- **Voltaren® Gel (diclofenac sodium gel, 1%)**: Amneal Pharmaceuticals’ has launched their generic version of Endo’s Voltaren gel. Voltaren Gel is a topical non-steroidal anti-inflammatory drug (NSAID) that is indicated for the relief of osteoarthritis. According to IMS Health, Voltaren Gel had approximately $413 million in annual U.S. sales.


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