New drug information

- **Duobrii™ (halobetasol propionate and tazarotene):** The U.S. Food and Drug Administration (FDA) approved Ortho Dermatologics’ Duobrii for the topical treatment of plaque psoriasis. Halobetasol and tazarotene as single entities are available generically and as branded products. Ortho Dermatologics believes that Duobrii has the potential to delay some patients from switching to more expensive biologic treatment which could potentially result in health care savings.1 Duobrii launched at an annual wholesale acquisition cost (WAC) of $825 per 100 gram tube which is about 50% lower than other branded topical combination products.1

- **Qternmet XR™ (dapagliflozin, saxagliptin and metformin hydrochloride):** AstraZeneca received FDA approval for Qternmet XR as an oral adjunct treatment to diet and exercise to improve glycemic control in adults with type 2 diabetes. Qtern® (dapagliflozin and saxagliptin) was approved in March 2017. AstraZeneca anticipates Qternmet XR may benefit patients who require improved glycemic control by adding an SGLT-2 inhibitor and DPP-4 inhibitor to metformin in a once-daily tablet.2 Launch plans are pending.

- **Nayzilam® (midazolam):** UCB received FDA approval of Nayzilam nasal spray for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient’s usual seizure pattern in patients with epilepsy 12 years of age and older. Nayzilam is a single-use treatment to be carried by the patient and can be administered by a non-health care professional in patients actively seizing. Nayzilam is administered as one spray (5 mg) into one nostril; one additional spray into the opposite nostril may be administered after 10 minutes if the patient has not responded to the initial dose. Prior to this approval, Valeant Pharmaceuticals’ Diastat® (diazepam rectal gel) was the only FDA-approved non-intravenous medication for acute seizures. Launch plans are pending.

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Generic drug information

- **Vesicare® (solifenacin):** Multiple manufacturers have launched their generic versions of Astellas’ Vesicare for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. Vesicare generated $955 million in U.S. annual sales in 2018.

- **Delzicol® (mesalamine DR):** Teva has launched the first generic version of Allergan’s Delzicol for the treatment of certain patients with ulcerative colitis. It is unclear when other generic versions of Delzicol will launch. Greenstone launched an authorized generic version of Delzicol in May 2019. Delzicol generated $133 million in U.S. annual sales in 2018.

- **Cuprimine® (penicillamine):** Amerigen Pharmaceuticals launched the first generic version of Bausch Health’s Cuprimine for the treatment of Wilson’s disease, cystinuria, and in certain patients with rheumatoid arthritis. No other generic manufacturers appear to be pursuing generic versions of Cuprimine. Oceanside launched an authorized generic version in May 2019. In 2018, Cuprimine had $127 million in U.S. annual sales.

- **Lotemax® (loteprednol) ophthalmic suspension:** The first generic version of Bausch Health’s Lotemax ophthalmic suspension 0.5% for the treatment of steroid responsive inflammatory conditions of the conjunctiva and for the treatment of post-operative inflammation following ocular surgery was launched by Akorn. No other manufacturers are anticipated to launch generic versions in 2019. Lotemax gel and ointment do not have generic versions available, but the gel may see generic competition in 2019. In 2018, Lotemax ophthalmic suspension had $118 million in U.S. annual sales.

- **Mifeprex® (mifepristone):** GenBioPro launched the first generic version of Danco Laboratories’ Mifeprex for the medical termination of pregnancy. Upon approval of the generic product, the FDA modified the existing REMS for Mifeprex to establish a single, shared system REMS for mifepristone products.3

- **Tarceva® (erlotinib):** Mylan and Teva both launched generic versions of Genentech’s Tarceva for the treatment of certain patients with metastatic non-small cell lung cancer or pancreatic cancer. Multiple manufacturers are set to launch their generic versions in November 2019. Tarceva generated $226 million in U.S. annual sales in 2018.

- **Tracleer® (bosentan):** Multiple manufacturers launched their generic version of Actelion Pharmaceuticals’ Tracleer for the treatment of certain patients with pulmonary arterial hypertension. In 2018, Tracleer generated $268 million in U.S. annual sales.

*Specialty medication

References

2. https://www.in-pharmatechnologist.com/Article/2019/05/14/FDA-approved-AstraZeneca-s-Qternmet-XR

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