New drug information

● **Sympazan™ (clobazam oral soluble film):** The Food and Drug Administration (FDA) approved Aquestive Therapeutics’ Sympazan for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in pediatric patients ages two years and older. Sympazan is the first oral soluble film formulation of clobazam, Lundbeck’s Onfi® (clobazam) and generics versions are available in tablets and oral suspension. Sympazan will also compete in the LGS market with Eisai’s Banzel® (rufinamide) and GW Pharmaceuticals recently approved Epidiolex® (cannabidiol).

● **Xofluza™ (baloxavir marboxil):** The FDA approved Genetech/Roche’s Xofluza for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours. Compared with Roche’s Tamiflu® which is dosed orally twice daily for five days, Xofluza is a single dose oral medication. The wholesale acquisition cost (WAC) of a course of treatment with either Tamiflu or Xofluza is $150, generic versions of Tamiflu cost ~$100 per course of treatment.¹

● **Bijuva™ (estradiol and progesterone):** The FDA approved Therapeutics MD’s Bijuva, an oral soft gel capsule, for women with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause. Bijuva is the first approved bio-identical combination of estradiol and progesterone. Bio-identical refers to estradiol and progesterone that are molecularly identical to the hormones produced naturally in the body. Bijuva is set to launch in the second quarter of 2019.²

● **Qmiiz ODT™ (meloxicam orally disintegrating tablets):** TerSera Therapeutics received FDA approval for Qmiiz, an orally disintegrating tablet meloxicam formulation indicated for treatment of the signs and symptoms of osteoarthritis (OA) in adults, rheumatoid arthritis (RA) in adults, and pauciarticular and polyarticular course juvenile rheumatoid arthritis (JRA) in pediatric patients who weigh greater than or equal to 60 kg. Meloxicam is also available as generic tablets and brand name Vivlodex® (Iroko Pharmaceuticals) capsules.

● **Dsuvia™ (sufentanil):** The FDA approved AcelRx Pharmaceuticals pain medication Dsuvia for use in adults in a certified medically supervised health care setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatment are inadequate. Dsuvia is a sublingual tablet housed in a disposable, single-dose applicator (SDA) and is 10 times stronger than fentanyl. Dsuvia is only to be administered by a health care provider and is not for use for more than 72 hours. The company expects the pill to be available early next year at a price of $50 to $60 per pill.³

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continued
New drug information continued

- **Aemcolo™ (rifamycin):** The FDA approved Cosmo Technologies’ Aemcolo for the treatment of adult patients with travelers’ diarrhea caused by noninvasive strains of Escherichia coli (E. coli), not complicated by fever or blood in the stool. Aemcolo will compete to gain market share with Valeant’s Xifaxan (rifaximin)® also indicated for travelers’ diarrhea. Aemcolo is set to launch in the first quarter of 2019.4,5

- **Yupelri™ (revefenacin):** Mylan and Theravance Biopharma received FDA approval for Yupelri, a long-acting muscarinic agent (LAMA) for maintenance treatment of patients with chronic obstructive pulmonary disease. Yupelri is administered once daily via a standard jet nebulizer. It is the first once-daily nebulized bronchodilator to be approved for COPD in the United States. Sunovion Pharmaceuticals’ Lonhala Magnair®, also a nebulized LAMA, is administered twice daily.6

Generic drug information

- **Onfi® (clobazam tablet):** Hikma, Upsher-Smith, Camber Pharmaceuticals, Taro, Breckenridge and Amneal Pharmaceuticals launched their generic versions of Onfi tablets which are approved as adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients two years of age or older. Onfi tablets generated $537 million in U.S. annual sales in 2017.

- **Onfi® (clobazam suspension):** Hikma, Upsher-Smith, and Amneal Pharmaceuticals launched their generic versions of Onfi suspension, indicated as adjunctive treatment for seizures associated with Lennox-Gastaut syndrome (LGS) in patients two years of age or older. Onfi suspension generated $215 million in U.S. annual sales in 2017.

- **Glycate (glycopyrrolate) tablets:** Foxland Pharmaceuticals launched the first generic for Carwin Associates’ Glycate for the treatment of peptic ulcer disease.

- **Minivelle® (estradiol patch):** Mylan and Noven Therapeutics launched their generic versions of Noven Therapeutics’ Minivelle patch for treatment of moderate to severe vasomotor symptoms due to menopause and for prevention of postmenopausal osteoporosis. Minivelle generated $111 million in U.S. annual sales in 2017.

- **Solodyn® (minocycline ER 24hr):** Oceanside Pharmaceuticals launched an authorized generic version of Valeant’s Solodyn 55 mg tablet for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. Solodyn generated $62 million for this strength in U.S. annual sales in 2017.

- **Vusion® (miconazole/zinc oxide/white petrolatum ointment):** Prestium Pharma launched an authorized generic version of Prestium Pharma’s Vusion as adjunctive treatment of diaper dermatitis when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast) in immunocompetent pediatric patients four weeks and older. Vusion had annual U.S. sales of less than $10 million in 2017.

References


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