New drug information

● **Nocdurna® (desmopressin):** Ferring Pharmaceuticals received U.S. Food and Drug Administration (FDA) approval of Nocdurna for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void. Nocdurna is the first sublingual tablet approved for this indication. Nocdurna will launch in the second half of 2018 and will be available in 2 dosage strengths: 27.7 mcg for women and 55.3 mcg for men. Women have a recommended lower dose as they were more sensitive to the effects of Nocdurna and had a higher risk of hyponatremia with the higher dose in clinical trials.

● **Epidiolex® (cannabidiol):** The FDA approved GW Pharmaceuticals Epidiolex for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients 2 years of age or older. Epidiolex is the first FDA approved formulation of plant-derived cannabidiol (CBD). Epidiolex is not associated with intoxication or euphoria that is associated with marijuana. CBD is a Schedule I substance because it is a chemical component of the cannabis plant. GW Pharmaceuticals is awaiting rescheduling by the U.S. Drug Enforcement Agency (DEA) before launch which is anticipated in September 2018.

● **Zemdri™ (plazomicin):** Achaogen received FDA approval of Zemdri for the treatment of patients 18 years of age or older with complicated urinary tract infections (cUTI) including pyelonephritis. Zemdri is a IV infusion administered over 30 minutes every 24 hours. Only limited clinical safety and efficacy data are available, as such, Zemdri should be reserved for use in patients who have limited or no alternative treatment options.

● **Qbrexa (glycopyrronium tosylate):** The FDA approved Dermina’s Qbrexa for the topical treatment of primary axillary hyperhidrosis (excessive sweating) in adults and pediatric patients 9 years of age and older. Qbrexa is available as a topical single-use cloth that can be applied once daily.

● **Aristada Initio™ (aripiprazole lauroxil):** Alkermes received FDA approval of their Aristada Initio Kit which is used in combination with oral aripiprazole and is indicated for the initiation of Aristada when used for the treatment of schizophrenia in adults. Aristada Initio is administered by a health care professional by intramuscular injection as one 675 mg injection with one 30 mg dose of oral aripiprazole in conjunction with the first Aristada® injection.

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New drug information (continued)

- **Tpoxx® (tecovirimat)**: Siga Technologies received FDA approval for its oral formulation of Tpoxx for the treatment of smallpox. Smallpox was eradicated in 1980; however, there are concerns that smallpox may be used as a bioweapon. Initially, Tpoxx will be available only through the U.S. government’s Strategic National Stockpile (SNS) of which 2 million courses have been delivered.1

- **Symtuza® (darunavir, cobicistat, emtricitabine, tenofovir alafenamide)**: The FDA approved Janssen’s once-daily Symtuza for the treatment of adult HIV patients who are either treatment-naïve or virologically suppressed on a stable antiretroviral regimen. Symtuza is the first complete, darunavir-based single-tablet regimen.

- **Krintafel® (tafenoquine)**: GlaxoSmithKline received FDA approval of Krintafel for the radical cure (prevention of relapse) of Plasmodium vivax malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute P. vivax infection. The recommended dose in patients aged 16 years and older is a single dose of 300 mg. Another tafenoquine application filed by 60 Degrees Pharmaceuticals is awaiting FDA review for the prevention of malaria in travelers.

- **Nuplazid® (pimavanserin)**: Acadia Pharmaceuticals received FDA approval for a new capsule dose formulation and new tablet strength for Nuplazid (pimavanserin) to treat patients with hallucinations and delusions associated with Parkinson’s disease psychosis. The 34 mg capsule will provide patients a one capsule once daily formulation option instead of the current administration of two 17 mg tablets once daily. The FDA approval of the 10 mg tablet provides a lower dosage strength in patients who are concomitantly receiving strong cytochrome 3A4 inhibitors which can inhibit the metabolism of Nuplazid.

- **Orilissa™ (elagolix)**: The FDA approved AbbVie’s Orilissa for the oral management of moderate to severe pain associated with endometriosis. An AbbVie spokesperson has said that the price will be set at about $850 per month. Abbvie expects Orilissa to launch during the first week of August.2

New generics

- **Uceris® (budesonide) extended-release (ER) tablets**: Actavis Pharma/Teva launched the first generic of Valeant’s Uceris for the induction of remission in patients with active, mild to moderate ulcerative colitis. According to IMS Health, Uceris generated $196 million in U.S. sales last year.

- **Welchol (colesevelam)**: Glenmark Pharmaceuticals launched their generic version of Sankyo’s Welchol packet for oral suspension. Welchol packets generated $73 million in U.S. sales last year according to IMS health.

References


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