New drug information

- **Dupixent® (dupilumab):** The Food and Drug Administration (FDA) approved Sanofi and Regeneron’s Dupixent for the treatment of adults with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Dupixent is the first biologic medication approved for the treatment of AD. The wholesale acquisition cost (WAC) of Dupixent in the United States is $37,000 annually. This is less than other frequently utilized biologic medications for the treatment of different skin disorders, such as Humira® or Enbrel®.¹

- **Ocrevus™ (ocrelizumab):** The FDA approved Ocrevus for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis (PPMS). Ocrevus, an intravenous (IV) formulation given every 6 months, is the first drug FDA approved for patients with PPMS. The annual WAC is $65,000 per year, a 20 percent discount on average to competitors.²

- **Zejula™ (niraparib):** Tesaro received FDA approval of Zejula for the once daily maintenance treatment of women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Zejula is the first poly(ADP-ribose) polymerase (PARP) inhibitor that does not require BRCA mutation or other biomarker testing. Tesaro anticipates launching Zejula in the United States in late April.

- **Austedo™ (deutetrabenzine):** The FDA approved Teva’s Austedo for the treatment of chorea associated with Huntington’s disease (HD), a neurodegenerative movement disorder that impacts cognition, behavior, and movements. Xenazine® (tetrabenazine) is the only other product approved for HD. Austedo is the deuterated form of Xenazine which allows for decreasing the three times a day dosing used for Xenazine to the twice daily dosing of Austedo. Austedo and Xenazine share similar boxed warnings within their prescribing information, warning of increased risk of depression and suicidal thoughts and behavior. The WAC of Austedo is lower than the brand name Xenazine, and depending on the dose, is similar or lower in cost to the generic versions of Xenazine. The FDA has granted priority review for deutetrabenazine for the treatment of tardive dyskinesia and assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 30, 2017.

- **Ingrezza™ (valbenazine):** Neurocrine received FDA approval for Ingrezza, the first medicine approved for the treatment of tardive dyskinesia. Ingrezza, Xenazine, and Austedo are all vesicular monoamine transporter 2 (VMAT2) inhibitors. However, in addition to the difference in indications, Ingrezza is dosed once daily compared with Austedo (twice daily) and Xenazine (three times daily). Also, Ingrezza does not have a boxed warning; both Austedo and Xenazine have a boxed warning. Launch is expected around May 1 and Neurocrine reports Ingrezza will be competitively priced to Austedo.³

- **Bevencio® (avelumab):** The FDA approved EMD Serono and Pfizer’s Bevencio for IV use for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC). Bevencio is approved under accelerated approval on tumor response and duration of response and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials. Bevencio is the first FDA-approved treatment for mMCC, a rare, aggressive form of skin cancer.

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New indications

- **Sovaldi® (sofosbuvir):** The FDA granted approval of Gilead’s Sovaldi for the treatment of hepatitis C (HCV) in pediatric patients ages 12 – 17 who weigh at least 77 pounds (35 kg). Prior to this approval, the use of Sovaldi was already approved for the treatment of HCV in adults.

- **Harvoni® (ledipasvir/sofosbuvir):** The FDA granted approval of Gilead’s Harvoni for the treatment of hepatitis C (HCV) in pediatric patients ages 12 – 17 who weigh at least 77 pounds (35 kg). Prior to this approval the use of Harvoni was already approved for the treatment of HCV in adults. Sovaldi and Harvoni are the first direct-acting antiviral treatments approved for pediatric HCV patients.

- **Lucentis® (ranibizumab):** The FDA has expanded the indication of Genetech’s Lucentis to include all forms of diabetic retinopathy with or without diabetic macular edema (DME). Prior to this approval, Lucentis had been approved to treat diabetic retinopathy just in patients with DME. Lucentis is also approved to treat:
  - Neovascular (wet) age-related macular degeneration
  - Macular edema following retinal vein occlusion
  - DME and
  - Myopic choroidal neovascularization

April news

- “The U.S. Food and Drug Administration (FDA) is poised to make a comeback from the relatively low number of new drugs approved in 2016, though it’s unlikely to match the approval highs from 2014 and 2015. Already in 2017, FDA has approved 14 new drugs, though that quick pace is not likely to continue and the rest of the year is shaping up to be an average or slightly above average year for approvals.”

- “Eli Lilly and Company and Incyte Corporation announced today that the FDA has issued a complete response letter for the New Drug Application (NDA) of the investigational medicine baricitinib, a once-daily oral medication for the treatment of moderate-to-severe rheumatoid arthritis (RA).”

- “PTC Therapeutics, Inc. announced it has completed its acquisition of all rights to Emflaza™ (deflazacort) for the treatment of Duchenne muscular dystrophy (DMD) in the U.S. Execution of the asset purchase agreement setting forth the terms of the acquisition was announced on March 16, 2017.”

- “Anticipating an FDA approval later this year for a promising hereditary angioedema med from CSL, Shire has taken a preemptive strike at the Australian drugmaker. In a new lawsuit, it’s asking a court to block the launch.”

References


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