New approvals

- **Lutathera® (lutetium Lu 177 dotatate):** The Food and Drug Administration (FDA) approved Advanced Accelerator Applications’ Lutathera for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. Lutathera is administered every 8 weeks for a total of 4 doses. Lutathera is a radiopharmaceutical: it should be used by or under control of physicians who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals.

- **Symdeko™ (tezacaftor/ivacaftor); (ivacaftor) tablets:** Vertex received FDA approval for Symdeko for the treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Symdeko. Symdeko is co-packaged as tezacaftor 100 mg/ivacaftor 150 mg fixed dose combination tablets and ivacaftor 150 mg tablets. Symdeko is dosed as 1 tablet (tezacaftor 100 mg/ivacaftor 150 mg) in the morning and 1 tablet (ivacaftor 150 mg) in the evening. Symdeko should be taken with fat-containing food. The annual wholesale acquisition cost (WAC) for Symdeko was set at $292,000. Vertex also manufactures Orkambi and Kalydeco for cystic fibrosis which have annual WACs of $272,000 and $311,000.¹

- **Erleada™ (apalutamide):** The FDA approved Erleada for the treatment of patients with prostate cancer that has not spread (non-metastatic), but that continues to grow despite treatment with hormone therapy (castration-resistant). This is the first FDA-approved treatment for non-metastatic, castration-resistant prostate cancer.

New indications

- **Trulance® (plecanatide):** Synergy Pharmaceuticals received FDA approval of Trulance for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults. Prior to this approval, Trulance was only FDA approved for the treatment of adults with chronic idiopathic constipation (CIC).

- **Opdivo® (nivolumab):** The FDA approved BMS’ Opdivo for treatment of patients with melanoma who are at high risk of disease recurrence following complete surgical resection. This is the first approval for a programmed death-1 (PD-1) immune checkpoint inhibitor as an adjuvant treatment for any cancer.
New indications (continued)

- **Zomacton® (somatropin):** Ferring Pharmaceuticals’ Zomacton received FDA approval for the replacement of growth hormone (GH) in adults with GH deficiency. Zomacton was first indicated for the treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone.

- **Feraheme® (ferumoxytol injection):** The FDA indication for AMAG’s Feraheme now includes all eligible adult patients with iron deficiency anemia (IDA) who are intolerant of or have not responded adequately to oral iron therapy. Prior approval included adult patients with IDA and chronic kidney disease.

- **Zytiga® (abiraterone acetate):** The FDA expanded the approval for J&J’s Zytiga for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer in combination with prednisone. Zytiga was first approved in combination with prednisone for the treatment of men with metastatic castration-resistant prostate cancer.

- **Imfinzi® (durvalumab):** AstraZeneca received FDA approval for Imfinzi to treat locally advanced, stage 3, unresectable non-small cell lung cancer that has not progressed following platinum-based chemoradiation. Imfinzi is the first immunotherapy approved to reduce the risk of the cancer progressing in this setting. Imfinzi first received accelerated approval for locally advanced or metastatic bladder cancer.

February news

- “Apricus Biosciences received a Complete Response Letter (CRL) from the FDA regarding its marketing application for topical erectile dysfunction cream Vitaros™ (alprostadil).”

- “Vertex Pharmaceuticals Incorporated announced the selection of two next-generation correctors, VX-659 and VX-445, to advance into Phase 3 development as part of two different triple combination regimens for people with cystic fibrosis.”

- “Novartis’s Sandoz division has won U.S. approval for a larger dosage of its Glatopa® drug for multiple sclerosis (MS) patients, ending a costly delay that allowed rival generics makers to beat it to market.”

- “Just 8 months after Sanofi amended its deal with ImmunoGen, paying $30 million to get full commercial rights on isatuximab and SAR428926—an anti-LAMP1 ADC for solid tumors—the pharma giant is disposing a pair of development programs once pursued for both drugs.”

- “Salix Pharmaceuticals, one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases and a wholly owned subsidiary of Valeant Pharmaceuticals International, Inc., and its partner Norgine have received notice that the FDA has extended the PDUFA action date for its review of the New Drug Application for PLENVU® (NER1006) by three months to May 13, 2018.”

References


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