New approvals

- **Triptodur™ (triptorelin):** Arbor Pharmaceuticals announced the U.S. Food and Drug Administration (FDA) approval of Triptodur for the treatment of pediatric patients 2 years and older with central precocious puberty (CPP). Triptodur is a 6-month extended release intramuscular injection that has been shown to arrest or reverse the clinical signs of puberty.

- **Verzenio™ (abemaciclib):** The FDA approved Eli Lilly’s Verzenio in combination with fulvestrant for the treatment of women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer with disease progression following endocrine therapy, and as monotherapy for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting. It is the first CDK4/6 inhibitor FDA approved as monotherapy. Verzenio's wholesale acquisition cost (WAC) will be about $10,948 which is similar to Novartis' Kisqali 600 mg dose and lower than Pfizer’s Ibrance. Verzenio is associated with high rates of diarrhea which may be treated with over-the-counter loperamide and tends to reverse after a few days.¹

- **Yescarta™ (axicabtagene ciloleucel):** The FDA approved Kite Pharma’s Yescarta (axicabtagene ciloleucel) for the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. It is not indicated for the treatment of patients with primary central nervous system lymphoma. Yescarta is a CD19-directed genetically modified autologous T-cell immunotherapy, also known as chimeric antigen receptor (CAR) T-cell therapy. The list price of Yescarta is $373,000 for one course of treatment.² There are additional therapy costs associated with the administration of Yescarta which are not included in the list price (e.g. leukapheresis, conditioning chemotherapy regimen, hospital stay, adverse event treatment with Actemra®, etc). Yescarta will only be available for administration at certified healthcare facilities.
New indications

- **Rapivab® (peramivir):** The FDA approved BioCryst’s intravenous Rapivab, for the treatment of acute uncomplicated influenza to pediatric patients 2 years and older who have been symptomatic for no more than 2 days. Prior to this approval, it was approved in patients 18 years and older.

- **Liletta® (levonorgestrel-releasing intrauterine system) 52 mg:** The FDA expanded the duration of use of Allergan’s Liletta for the prevention of pregnancy from 3 years up to 4 years.

- **Keytruda® (pembrolizumab):** The FDA approved Keytruda for the treatment of patients with recurrent locally advanced or metastatic gastric of gastroesophageal junction whose tumors express PD-L1 with disease progression on or after 2 or more prior lines of therapy. This indication is approved under the FDA’s accelerated approval regulations based on tumor response rate and durability of response.

- **Opdivo® (nivolumab):** Bristol-Myers Squibb’s announced the accelerated approval of Opdivo for the treatment of hepatocellular carcinoma patients previously treated with sorafenib. This is the first immuno-oncology agent to receive this approval.

- **Privigen® (Immune Globulin Intravenous [Human], 10% liquid):** CSL Behring announced the FDA approval of Privigen for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability.

- **Stelara® (ustekinumab):** Janssen announced that Stelara was FDA approved to treat moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy in pediatric patients aged 12 and older.

- **Simponi Aria® (golimumab):** The FDA approved Janssen’s Simponi Aria for the treatment of adults with active psoriatic arthritis or active ankylosing spondylitis. Prior to this approval Simponi Aria was approved for moderately to severely active rheumatoid arthritis.

- **Soliris® (eculizumab):** The FDA approved Soliris as a treatment for adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody-positive. These patients represent approximately 5-10% of all patients with MG.
October news

- The monoclonal antibody HIV drug ibalizumab, designed for patients who've developed severe drug resistance, had long-lasting protection in the 24-week extension phase of a phase III trial.⁴

- The FDA has accepted the Biologics License Application (BLA) for burosumab to treat pediatric and adult patients with X-linked hypophosphatemia. The drug was also granted a Priority Review status, so it will be reviewed within 6 months instead of the customary 10 months; its Prescription Drug User Fee Act (PDUFA) action date is April 17, 2018.⁵

- An FDA advisory committee voted 16-0, with one abstention, in favor of recommending approval of semaglutide, a GLP-1 receptor agonist for once-weekly injection in type 2 diabetes along with lifestyle changes.⁶

- “After decades of research, a gene therapy to correct a specific genetic mutation is on the brink of being approved by the FDA. Spark Therapeutics’ Luxturna™ for an inherited form of blindness was unanimously backed by an advisory committee, despite questions from agency reviewers about the clinical endpoints used in the biotech’s pivotal trial and safety, and the FDA will now decide whether to green light it by Jan. 12.”⁷

References


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