New drug information

- **Lutrate® (leuprolide acetate) Depot Kit**: The Food and Drug Administration (FDA) approved GP Pharm’s Lutrate for palliative treatment of advanced prostate cancer. Lutrate is administered by intramuscular (IM) injection every three months. Lutrate is available in 23 countries in Europe, but the U.S. launch plans have not been released. Similar medications with this indication include Abbvie’s Lupron® and Tolmar Pharmaceuticals’ Eligard®.

- **Panzyga™ (immune globulin intravenous [IV], human)**: The FDA approved Octapharma’s Panzyga for treatment of primary humoral immunodeficiency (PI) and chronic immune thrombocytopenia (ITP) in adults. Panzyga is for IV use only and uses weight-based dosing.

- **Copiktra™ (duvelisib)**: FDA approved Verastem’s twice-daily oral Copiktra for the third-line treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) and accelerated approval for third-line treatment of relapsed or refractory follicular lymphoma (FL). These indications are similar to Gilead Sciences’ Zydelig®. Both drugs contain multiple boxed warnings including, but not limited to: fatal and serious infection, diarrhea or colitis, and pneumonitis.

- **Vizimpro™ (dacomitinib)**: FDA approved Pfizer’s once-daily oral Vizimpro as the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations. In a clinical trial, Vizimpro improved progression-free survival by a median of about 6 months more than AstraZeneca’s Iressa® (gefitinib), but there was no improvement in overall response rate or overall survival. Other competitors of Vizimpro include: Boehringer Gilotrif®, Astella’s Tarceva®, and Aerie Pharmaceuticals’ Tagrisso®.

- **Libtayo™ (cemiplimab-rwlc)**: The FDA approved the sixth programmed-death inhibitor immuno-oncologic in Regeneron Pharmaceuticals’ Libtayo for treatment of metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. This is the first FDA approval for advanced CSCC. Libtayo is administered via IV infusion every 3 weeks with a wholesale acquisition cost (WAC) of $9,100 per 3-week cycle.
New drug information continued

- **Arikayce™ (amikacin liposome inhalation suspension):** The FDA granted accelerated approval to Insmed’s Arikayce as part of a combination antibacterial drug regimen for the treatment of Mycobacterium avium complex (MAC) lung disease in adults who have limited or no alternative treatment options who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multi-drug background regimen therapy. Although there are injectable and oral aminoglycoside antibiotics available, Arikayce is the only inhaled antibiotic available for treatment of MAC. Arikayce launched at an annual WAC of ~$132,500.

- **Tegsedi™ (inotersen):** The FDA approved Ionis Pharmaceuticals’ Tegsedi for treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults. Tegsedi is available in a prefilled syringe to be self-administered once weekly by subcutaneous injection. Alynylam’s Onpattro®, also approved for hATTR, is intravenously administered by a medical professional every 3 weeks. Tegsedi patients must have their platelets monitored once a week due to possible thrombocytopenia and their renal function monitored every 2 weeks due to possible glomerulonephritis. Both Tegsedi and Onpattro have annual WACs of $450,000.

- **Revcovi™ (elepegademase-lvlr) intramuscular injection:** The FDA has approved a recombinant enzyme replacement therapy (ERT) in Leadiant Biosciences’ Revcovi for the treatment of pediatric and adult patients with adenosine deaminase severe combined immunodeficiency (ADA-SCID). Leadiant plans to discontinue Adagen®, a bovine ERT approved for ADA-SCID, and transition patients to Adagen.1 Leadiant anticipates launching Revcobi by the end of 2018.

- **Yutiq™ (flucinolone acetonide, sustained-release Durasert implant):** The FDA approved EyePoint’s Yutiq for the treatment of chronic noninfectious uveitis affecting the posterior segment of the eye. Yutiq is a 3-year sustained release intravitreal implant that is administered in a physician’s office. EyePoint plans to launch Yutiq in the first quarter of 2019.²

- **Talzenna™ (talazoparib):** The FDA approved Pfizer’s once-daily oral Talzenna for the treatment of locally advanced or metastatic breast cancer associated with breast cancer gene (BRCA) mutation in HER2 negative genotype. Talzenna is the only drug that targets HER2 negative genotype patients in this class. AstraZeneca’s Lynparza is another drug with the same indication that is not specific for HER2 negative genotype. Pfizer plans to launch Talzenna in October 2018 at an annual WAC of ~$175,000.³

- **Khapzory™ (levoleucovorin) for IV use:** Spectrum Pharmaceuticals received FDA approval of Khapzory to prevent harmful effects of certain chemotherapy regimens. As reported by Spectrum, Khapzory is the first levoleucovorin product that contains sodium in its formulation. Launch is planned for January 2019.⁴ Levoleucovorin is also available as Fusilev (Spectrum) and from multiple generic manufacturers.

New indications

- **GamaSTAN® (immune globulin [human]):** The FDA approved a new formulation of Grifols’ GamaSTAN for patients who have been exposed to hepatitis A virus and measles.

- **Fycompa® (perampanel):** The FDA expanded Eisai’s Fycompa for use in children ages 4 years and older as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy. Prior to this approval, the indication only included children from 12 years of age and older.

- **Humira® (adalimumab):** The FDA expanded Abbvie’s Humira indication for the treatment of uveitis to include pediatric patients 2 years and older. Humira had prior approval in uveitis in adult patients only.
New indications continued

- **Hemlibra® (emicizumab-kxwh):** The FDA approved Roche’s Hemlibra for routine prophylaxis to prevent or reduce the frequency of bleeding episodes to include hemophilia A patients without factor VIII inhibitors. Hemlibra was initially approved only for hemophilia A patients with factor VIII inhibitors.

- **Xarelto® (rivaroxaban):** The FDA approved Janssen’s Xarelto 2.5 mg twice daily to be used in combination with low-dose aspirin, to reduce the risk of major cardiovascular (CV) events (CV death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (CAD/PAD).

- **Dupixent® (dupilumab):** The FDA approved Regeneron/Sanofi’s Dupixent as an add-on maintenance treatment in patients with moderate-to-severe asthma, aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma. Prior to this approval, Dupixent was approved for the treatment of adults with moderate-to-severe atopic dermatitis.

- **Rituxan® (rituximab):** Genentech received FDA approval of Rituxan for the treatment of adult patients with microscopic polyangiitis and granulomatosis with polyangiitis who have achieved disease control using induction therapy.

October news

- “Counterbalancing Novartis’ otherwise positive third quarter earnings, the Swiss pharma giant disclosed Thursday that regulators rejected an application aimed at getting its drug canakinumab approved for cardiovascular risk reduction.”

- “The FDA has granted a priority review to a New Drug Application (NDA) for selinexor for the treatment of patients with penta-refractory multiple myeloma, according to Karyopharm Therapeutics, the manufacturer of the XPO1 inhibitor.”

- “AveXis, a Novartis company, reported that it has submitted a Biologics License Application (BLA) to the FDA requesting approval of AVXS-101 to treat infants with spinal muscular atrophy (SMA) type 1.”

- “Shire announced that the FDA Gastrointestinal Drugs Advisory Committee voted unanimously (10 to 0) that the risk-benefit profile of prucalopride supports the approval of this NDA. The FDA will take the advisory committee’s recommendation into consideration when the agency makes a final determination. The Prescription Drug User Fee Act (PDUFA) action date for prucalopride is December 21, 2018.”

- “Biosimilar developer Sandoz announced that it had reached a global settlement of its patent disputes with AbbVie, maker of the reference Humira. The settlements will allow Sandoz to enter some European markets with its biosimilar adalimumab, Hyrimoz, as early as October 16, 2018. While the terms of the agreement allow for European sales of the drug to commence this month, U.S. patients will have to wait for biosimilar adalimumab; AbbVie’s provision of a nonexclusive license to sell adalimumab will not begin in the United States until September 30, 2023.”

- “The BLA for Viaskin Peanut (DBV Technologies) has been submitted to the FDA for the treatment of peanut allergy in children 4–11 years old.”

References


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