New approvals

- **Pemfexy™ (pemetrexed) Ready-to-Dilute**: Eagle Pharmaceuticals announced that the U.S. Food and Drug Administration (FDA) granted tentative approval of Pemfexy for certain types of non-small cell lung cancer (NSCLC) and malignant pleural mesothelioma. Pemfexy does not require reconstitution; where Eli Lilly’s Alimta® (pemetrexed) must be reconstituted. Tentative approval means that the FDA has concluded that a drug product has met all required standards, but is not eligible for marketing in the United States because of existing patent protections. Final approval may be granted once the patent litigation between Eagle and Eli Lilly is resolved.

- **Fasenra™ (benralizumab)**: The FDA approved AstraZeneca’s Fasenra for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Fasenra is administered by subcutaneous injection every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter. Fasenra should be administered by a health care professional.

- **Mepsevii™ (vestronidase alfa)**: Ultragenyx received FDA approval for Mepsevii for the treatment of children and adults with mucopolysaccharidosis VII (MPS VII); also known as Sly syndrome. This is the first medication approved for MPS VII. Mepsevii is an enzyme replacement therapy designed to replace the deficient lysosomal enzyme beta-glucuronidase in MPS VII patients of which there are approximately 200 individuals worldwide. Ultragenyx reports that the average wholesale acquisition cost (WAC) will be $375,000 a year.¹

- **Hemlibra™ (emicizumab-kxwh)**: The FDA has approved Genetech’s Hemlibra for the routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors. Hemlibra is the first hemophilia medication available as a weekly self-administered subcutaneous injection. The reported wholesale acquisition cost (WAC) for a person weighing 127 pounds is approximately $482,000 for the first year, and $448,000 per year thereafter.² Genentech has reported that Hemlibra will launch as early as November 27, 2017.
**New approvals (continued)**

- **Tracleer® (bosentan) 32 mg**: Actelion Pharmaceuticals announced FDA approval for a new 32 mg tablet for oral suspension for use in pediatric individuals aged 3 years and older with idiopathic or congenital pulmonary arterial hypertension (PAH), to improve pulmonary vascular resistance (PVR), which is expected to result in improvement in exercise ability. Tracleer is the first FDA-approved medication for pediatric individuals with PAH. The tablet can be dispersed in a minimal amount of water before oral administration. Prior to this approval, Tracleer was available in 62.5 mg and 125 mg tablets and was only approved in the adult population.

**New indications**

- **Zelboraf® (vemurafenib)**: Roche received FDA approval for Zelboraf for the treatment of patients with Erdheim-Chester disease (ECD) with BRAF V600 mutation. ECD is a rare, serious blood disease characterized by the abnormal multiplication of histiocytes, a type of white blood cell, which can invade normal tissues and organs in the body. Zelboraf is the first treatment approved for ECD.

- **Alecensa® (alectinib)**: Roche received FDA approval for the first-line treatment of anaplastic lymphoma kinase-positive (ALK+) locally advanced/metastatic NSCLC. Prior to this indication, Alecensa was only approved for ALK+ NSCLC patients who have progressed on or are intolerant to Pfizer’s Xalkori® (crizotinib).

- **Sprycel® (dasatinib)**: Bristol-Myers Squibb received FDA approval for the treatment of pediatric patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. Prior to this indication, Sprycel was approved for use in adult patients with Ph+ CML and Ph+ acute lymphoblastic leukemia (ALL).

- **Adcetris® (brentuximab vedotin)**: The FDA approved Seattle Genetics and Takeda’s Adcetris for patients with primary cutaneous anaplastic large cell lymphoma or CD30-expressing mycosis fungoides, which are the most common subtypes of cutaneous T-cell lymphoma (CTCL).

- **Faslodex® (fulvestrant)**: AstraZeneca received FDA approval for use with Eli Lilly’s Verzenio™ (abemaciclib), for the treatment of hormone receptor-positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer (MBC) in women with disease progression after endocrine therapy. This combination was previously approved under Verzenio’s label.

- **Sutent® (sunitinib)**: The FDA approved Pfizer’s Sutent as adjuvant treatment for adults at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy (kidney removal). This is the first adjuvant treatment approved for patients with RCC.
November news

- “Takeda Pharmaceutical has linked up with a Massachusetts-based medical device maker to develop a ‘needle-free’ approach to administering biologics, with plans to initially test the delivery system on its top-selling drug.”

- “Three-year follow-up data from the Phase 3 study evaluating Spark Therapeutics’ Luxurna® (voretigene neparvovec) in patients with biallelic RPE65-mediated inherited retinal disease showed a sustained treatment benefit. The results were presented at the AAO Retina Subspecialty Day.”

- “Celgene Corporation announced results from two phase 3 trials evaluating the efficacy and safety of the drug ozanimod. Ozanimod was invented by scientists at The Scripps Research Institute (TSRI). Ozanimod is a novel, oral, selective sphingosine 1-phosphate 1 (S1PR1) and 5 (S1PR5) receptor modulator, and was compared to the first-line treatment, Avonex® (interferon beta-1a) (IFN), in patients with relapsing multiple sclerosis (RMS). The findings from the two pivotal phase 3 (SUNBEAM and RADIANCE Part B) trials pave the way for ozanimod to enter the New Drug Approval process with the U.S. Food and Drug Administration (FDA).”

- “FDA’s Antimicrobial Drugs Advisory Committee voted against approval of Cipro® (ciprofloxacin) inhalation powder from Bayer to reduce exacerbations in adults with non-cystic fibrosis bronchiectasis and bacterial respiratory pathogens. The committee voted 9–6 and 14–1 that Bayer did not provide substantial evidence of the safety and effectiveness of 14- and 28-day Cipro regimens, respectively, in delaying the time to first pulmonary exacerbation after starting treatment.”

- “Lipocine Inc, a specialty pharmaceutical company, announced the FDA has extended the review period for Tlando™, the Company’s oral testosterone product candidate for the proposed indication of testosterone replacement therapy (TRT) in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. The FDA has assigned a new Prescription Drug User Fee Act (PDUFA) goal date of May 8, 2018.”

- “GlaxoSmithKline just inherited its biggest threat to Nucala® in the form of a new AstraZeneca rival. But the British drugmaker says it’s down for some marketplace battling. AstraZeneca’s Fasenra™ snagged an FDA approval last week for the treatment of severe eosinophilic asthma, and analysts have pegged its less frequent dosing as a potential advantage.”

References


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