NEW DRUG INFORMATION

● **Bonsity™ (teriparatide injection):** The U.S. Food and Drug Administration (FDA) approved Pfenex and Alvogen’s Bonsity for the treatment of osteoporosis in patients at high risk for fractures. Bonsity submitted under the 505(b)(2) regulatory pathway, with Lilly’s Forteo® (teriparatide injection) as the reference drug. Pfenex is asking the FDA to designate Bonsity as therapeutically equivalent (“A” rated) to Forteo, which would permit an automatic substitution in many states. Pfenex is conducting a comparative human factors study between Forteo and Bonsity that should be submitted by the end of October 2019 which would support an “A” rating. Launch and pricing depend on the FDA decision of therapeutic equivalence.

● **Beovu™ (brolucizumab-dbll):** Novartis’ Beovu received FDA approval for treatment of wet age-related macular degeneration (wet AMD). Beovu is the first FDA-approved anti–vascular endothelial growth factor (anti-VEGF) therapy to offer both greater fluid resolution compared to Regeneron Pharmaceuticals Eylea® (afibercept). Beovu also has the ability to maintain eligible wet AMD patients on a three-month dosing interval immediately after a three-month loading phase with uncompromised efficacy. Beovu is administered as an injection into the back of the eye by a health care professional. The recommended dose for Beovu is 6 mg once monthly for three months followed by 6 mg every 8–12 weeks. Novartis plans to launch Beovu in early November 2019. Beovu is expected to have a wholesale acquisition cost (WAC) of $11,100 for the first year, and $7,400 each year thereafter for patients on three-month dosing intervals.

● **Scenesse™ (afamelanotide):** The FDA approved Clinuvel Pharmaceuticals’ Scenesse, which is the first drug to increase pain-free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria. Scenesse is administered via a dissolvable implant inserted subcutaneously every two months. According to a Clinuvel spokesperson, “We refer pricing to our approach to pricing in Europe.” Scenesse is priced at approximately $15,695.19 per injectable implant, or $62,780.75 per patient based on four injectable implants per annum (excluding local taxes). Clinuvel will distribute the drug directly to hospitals within the year.

● **Bortezomib™ (bortezomib):** The FDA approved Dr. Reddy’s Bortezomib for the treatment of multiple myeloma, and mantle cell lymphoma who have received at least one prior therapy. Bortezomib was submitted under the 505(b)(2) regulatory pathway, with Takeda’s Velcade® (bortezomib) as the reference drug. Launch and pricing are pending.
● **Pemfexy™ (pemetrexed):** Eagle Pharmaceuticals’ Pemfexy received FDA approval for treatment of certain types of cancer. Pemfexy is a pemetrexed injection ready-to-dilute formulation for:

  → Locally advanced or metastatic nonsquamous non-small cell lung cancer in combination with cisplatin;

  → Locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy, as maintenance treatment;

  → Locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy as a single agent; and

  → Malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery in combination with cisplatin.

Pemfexy received tentative approval in 2017 after the FDA concluded the drug met all quality, safety and efficacy standards but was delayed due to patent litigation between Eagle and Eli Lilly. Eagle submitted Pemfexy under the 505(b)(2) regulatory pathway with Eli Lilly’s Alimta® (pemetrexed) as the reference medication. Launch and pricing pending.

● **Vumerity™ (diroximel fumarate):** The FDA approved Alkermes and Biogen’s Vumerity for the treatment of relapsing forms of multiple sclerosis (MS). Alkermes received tentative approval of Vumerity under the 505(b)(2) regulatory pathway, referencing Biogen’s Tecfidera® (dimethyl fumarate) data. Vumerity is a prodrug for monomethyl fumarate, which is the active metabolite of Tecfidera and may cause less gastrointestinal adverse events. Price and launch date pending.

● **Trikafta™ (elexacaftor/ivacaftor/tezacaftor):** Vertex’s Trikafta has been approved by the FDA for the treatment of cystic fibrosis (CF) patients 12 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. This mutation affects approximately 90% of the cystic fibrosis population or roughly 27,000 people in the United States. In clinical trials, CF patients treated with Trikafta experienced improvements in lung function. The wholesale annual cost (WAC) is $311,000 per year. Launch date is November 2019.

NEW INDICATIONS

● **Stelara® (ustekinumab):** The FDA granted approval for Johnson & Johnson’s Stelara to include treatment of moderately to severely active ulcerative colitis in adults.

● **Ultomiris® (ravulizumab-cwvz):** Ultomiris was granted expanded approval for the treatment of atypical hemolytic uremic syndrome (aHUS).

● **Wilate® (von Willebrand factor/coagulation factor VIII complex):** The FDA approved a new indication for Wilate for treatment of adults and adolescents with hemophilia A for routine prophylaxis to reduce the frequency of bleeding episodes and on demand treatment and control of bleeding episodes.
**OCTOBER NEWS**

- “The FDA came through with an OK for lasmiditan, branding it as Reyvow and lining it up — once a substance classification comes through from the DEA — for a major market release. The oral drug binds to 5-HT1F receptors and is designed to stop an acute migraine after it starts. That makes it a complementary therapy to their CGRP drug Emgality, which has a statistically significant impact on preventing attacks.”

- “In a stunning about-face, the company and its partners at Eisai say that a new analysis of a larger dataset on aducanumab has restored its faith in the drug as a game-changer for Alzheimer’s and, after talking it over with the FDA, they’ll now be filing for an approval of a drug that had been given up for dead.”

- “AstraZeneca paid a hefty price to partner with Daiichi Sankyo on their experimental antibody-drug conjugate for HER2 positive breast cancer. And they’ve been rewarded with a fast ride through the FDA, with a straight shot at creating another blockbuster oncology franchise.”

- “Ultragenyx Pharmaceutical Inc., a biopharmaceutical company focused on the development of novel products for serious rare and ultra-rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the company’s New Drug Application (NDA) for UX007 (triheptanoin) for the treatment of long-chain fatty acid oxidation disorders (LC-FAOD), a group of genetic disorders in which the body is unable to convert long-chain fatty acids into energy. The FDA has assigned a standard review designation with a Prescription Drug User Fee Act (PDUFA) target date of July 31, 2020.”

- “Japanese company Nippon Shinyaku has completed the submission of its rolling New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for viltolarsen, which is under development for the treatment of Duchenne muscular dystrophy (DMD) amenable to exon 53 skipping.”

**REFERENCES**