New drug information

- **Skyrizi™ (risankizumab-rzaa):** AbbVie's Skyrizi, a biologic that selectively blocks interleukin-23 (IL-23) received U.S. Food and Drug Administration (FDA) approval for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. It will directly compete with Janssen's Tremfya® and Sun's Illumya® in this market space as well as with other biologic drugs commonly used for plaque psoriasis (i.e., AbbVie’s Humira®, Novartis’ Cosentyx®, and J&J’s Stelara®). Skyrizi has an annual wholesale acquisition cost (WAC) of $88,500 for the first year which includes loading doses, and $59,000 yearly thereafter. AbbVie notes this is cheaper than most widely prescribed biologic treatment for moderate to severe plaque psoriasis.¹

- **Eticovo™ (etanercept-ykro):** The second biosimilar referencing Amgen/Pfizer's Enbrel® (etanercept) was approved by the FDA for Samsung Bioepis' Eticovo for the treatment of certain patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis; psoriatic arthritis; ankylosing spondylitis and plaque psoriasis. Sandoz's Erelzi is also a biosimilar referencing Enbrel. Neither Samsung Bioepis or Sandoz have released their launch plans; however, depending on patent litigation Enbrel could lose exclusivity either in 2019 or 2029.

- **Vyndaqel® (tafamidis meglumine) and Vyndamax™ (tafamidis):** Pfizer received FDA approval for both Vyndaqel and Vyndamax, for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. The FDA approved dose is either Vyndamax 61 mg (1 capsule) once daily, or Vyndaqel 80 mg (four-20 mg capsules) once daily, both achieve the same effectiveness in cardiomyopathy. The annual WAC for both is $225,000. Vyndaqel has launched and Vyndamax is expected to be available in the latter half of 2019. Pfizer plans to transition all patients to Vyndamax once sufficient supply is available.²

- **Fulvestrant™ (fulvestrant):** Fresenius Kabi USA received tentative FDA approval for an intravenous formulation of fulvestrant for the treatment of certain patients with hormone receptor (HR)-positive breast cancers. Fulvestrant is available generically as an intramuscular injection and from AstraZeneca as Faslodex®. It is unclear when full approval is expected for the intravenous formulation.

While the information in this newsletter is from sources we believe to be reliable, we do not warrant that the information in this document is free from error. Use it only as a guide. Statements regarding drugs or manufacturers are not intended as promotion; those statements should not be used to make assumptions about formulary status. Each trademarked drug name is the property of its respective owner.
New drug information (continued)

- **Ruzurgi™ (amifampridine):** Jacobus Pharmaceutical Company received FDA approval for Ruzurgi for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to less than 17 years of age. Evidence for this approval is based on studies in 32 adults with LEMS and pharmacokinetic modeling and simulation to determine the dosing regimen for pediatric patients. The only other FDA-approved drug for LEMS is Catalyst Pharmaceutical’s Firdapse™ which is indicated in adults. Firdapse has an annual WAC of $375,000. Jacobus has not released their launch plans for Ruzurgi but has said it will price Ruzurgi lower than Firdapse.¹

- **Zolgensma® (onasemnogene abeparvovec-xioi):** Novartis/AveXis Inc. received FDA approval for the one-time intravenous infusion treatment of Zolgensma, an adeno-associated virus vector-based gene therapy, for pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. Zolgensma is dosed based on the patient’s weight with an average WAC of $2,125,000 per one-time dose. Biogen’s Spinraza, a SMN2-directed antisense oligonucleotide, also treats SMA. It is given intrathecally with loading doses needed the first year and then administered every four months thereafter. Spinraza’s WAC for the first year of therapy is $750,000 with an annual WAC of $375,000 each subsequent year.⁴

New indications

- **Benlysta® (belimumab):** The FDA expanded GSK’s Benlysta IV infusion indication from adults only to include treatment of children aged 5 years and older with systemic lupus erythematosus (SLE). Benlysta is also approved as a subcutaneous injection in adults with SLE.

- **Bavencio® (avelumab):** EMD Serono received FDA approval for Bavencio in combination with PF Prism CV’s Inlyta® (axitinib) for the first-line treatment of patients with advanced renal cell carcinoma (RCC). Bavencio is also approved in patients with metastatic Merkel cell carcinoma and certain patients with locally advanced or metastatic urothelial carcinoma.

- **Mavyret® (glecaprevir and pibrentasvir):** The FDA expanded Abbvie’s label of Mavyret to include the treatment of six genotypes of hepatitis C virus (HCV) in children ages 12 to 17. Prior, Mavyret was only approved in the adult HCV population.

- **Tibsovo® (ivosidenib):** Agios received FDA approval for Tibsovo to be used as monotherapy for individuals aged 75 years or older with newly diagnosed acute myeloid leukemia (AML) who have isocitrate dehydrogenase-1 (IDH1) mutations as detected by an FDA-approved test or are ineligible for intensive induction chemotherapy. Tibsovo is also approved for the treatment of patients with relapsed or refractory AML.

- **Kalydeco® (ivacaftor):** Vertex Pharmaceuticals received FDA approval for Kalydeco for the treatment of children as young as six months old with cystic fibrosis (CF) who have at least one mutation in the CFTR gene. Previously, it was approved in CF patients 12 months and older.

- **Eylea® (aflibercept):** Regeneron received FDA approval for Eylea for the treatment of diabetic retinopathy. It was previously approved to treat neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion and diabetic macular edema.

- **Venclexta® (venetoclax):** Genentech and Abbvie’s Venclexta received FDA approval to expand its indication from previously treated patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) to untreated (first-line) treatment of CLL or SLL.

- **Gattex® (teduglutide, rDNA origin):** Shire received FDA approval for an expanded indication for Gattex for the treatment of pediatric patients aged 1 to 17 years old with short bowel syndrome (SBS) who are dependent on parenteral support. It was previously only approved in adults.

- **Cyramza® (ramucirumab):** The FDA approved Eli Lilly’s Cyramza as a single agent for the treatment of hepatocellular carcinoma (HCC) in patients who have an alpha fetoprotein (AFP) of ≥400 ng/mL and have been treated with Nexavar® (sorafenib). Cyramza is also FDA approved in gastric cancer, metastatic non-small cell lung cancer and metastatic colorectal cancer.
Specialty generic drug information

- **Cuprimine® (penicillamine):** Amerigen Pharmaceuticals launched the first generic version of Bausch Health’s Cuprimine for the treatment of Wilson’s disease, cystinuria, and in certain patients with rheumatoid arthritis. No other generic manufacturers appear to be pursuing generic versions of Cuprimine. Oceanside launched an authorized generic version in May 2019. In 2018, Cuprimine had $127 million in U.S. annual sales.

- **Tarceva® (erlotinib):** Mylan and Teva both launched generic versions of Genentech’s Tarceva for the treatment of certain patients with metastatic non-small cell lung cancer or pancreatic cancer. Multiple manufacturers are set to launch their generic versions in November 2019. Tarceva generated $226 million in U.S. annual sales in 2018.

- **Tracleer® (bosentan):** Multiple manufacturers launched their generic version of Actelion Pharmaceuticals’ Tracleer for the treatment of certain patients with pulmonary arterial hypertension. In 2018, Tracleer generated $268 million in U.S. annual sales.

May news

- “ADMA Biologics announces that the FDA has approved the Company’s Prior Approval Supplement (PAS) for Bivigam® (immune globulin intravenous (human), 10% liquid). The FDA’s approval of the PAS for Bivigam approves the use of the Company’s optimized intravenous immune globulin (IVIG) manufacturing process and enables ADMA to commence the marketing in the U.S. to patients with Primary Humoral Immunodeficiency (PI).”

- “Takeda Pharmaceutical Company Limited announced that the FDA has accepted for review a Biologics License Application (BLA) for a subcutaneous (SC) formulation of vedolizumab for maintenance therapy in adults with moderately to severely active ulcerative colitis (UC). Takeda proposes to make vedolizumab SC available in both pre-filled syringe and pen options.”

- “The FDA’s Oncologic Drugs Advisory Committee (ODAC) voted 8 – 3 against approving a new drug application (NDA) for quizartinib for adult patients with relapsed/refractory FLT3-ITD-positive acute myeloid leukemia (AML).”

- “The FDA’s ODAC voted 12 – 3 that the benefits of pexidartinib outweigh the risks for the treatment of adults with tenosynovial giant cell tumor not amenable to surgical resection.”

- “Novartis is looking to launch spinal muscular atrophy (SMA) gene therapy Zolgensma this year. But the possibility of a price tag as high as $5 million has already sparked controversy.”

- “Alexion Pharmaceuticals, Inc. announced that the New England Journal of Medicine (NEJM) published positive data from the Phase 3 PREVENT study of Soliris® (eculizumab), a first-in-class complement inhibitor, in adult patients with anti-aquaporin-4 (AQP4) auto antibody-positive neuromyelitis optica spectrum disorder (NMOSD). NMOSD is a rare and devastating, autoimmune, inflammatory disorder of the central nervous system (CNS) characterized by sudden and unpredictable relapses, also known as attacks.”

References

8. https://www.healio.com/hematology-oncology/sarcoma/news/online/%7B0f8a36bd-7745-4acf-bc3e-b26d0bc8a0b7%7D/fda-advisory-committee-supports-approval-of-pexidartinib-for-tenosynovial-giant-cell-tumor