New drug information

- **Evenity® (romosozumab-aqqg):** Amgen received U.S. Food and Drug Administration (FDA) approval for Evenity for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. Evenity has a Boxed Warning noting it may increase the risk of myocardial infarction, stroke and cardiovascular death. Evenity should be administered subcutaneously once a month by a health care provider for a maximum dosing period of one year as the bone forming effect wanes after 12 doses. Evenity will compete for market share with Radius Health’s Tymlos® (abaloparatide) and Eli Lilly’s Forteo® (teriparatide); both are self-administered subcutaneously once daily with dosing periods of 18 months or 24 months. Evenity launched at a WAC of $21,900 which is similar to the annual wholesale acquisition cost (WAC) of Tymlos. Forteo may lose exclusivity in August 2019 at which time it may face generic competition.

- **Mayzent® (siponimod):** Novartis received FDA approval for Mayzent, a once daily oral disease modifying therapy (DMT) for the treatment of relapsing forms of multiple sclerosis (MS) including clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS), and active secondary progressive disease (SPMS). Mayzent launched at an annual WAC of $88,500.

- **Mavenclad® (cladribine):** The FDA approved EMD Serono’s Mavenclad, an oral DMT, for the treatment of relapsing forms of MS including RRMS and SPMS. Because of its safety profile, it is not recommended in CIS; use is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. Mavenclad uses weight-based dosing administered in two treatment weeks (four to five consecutive days) about a month apart each year for two consecutive years. Mavenclad launched at an average annual WAC of $99,500. Mavenclad and Mayzent are the first oral medications approved for the treatment of SPMS.

- **Asceniv™ (immune globulin intravenous, human-sra) 10% liquid:** ADMA Biologics received FDA approval for Asceniv for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents 12 – 17 years of age. ADMA’s Bivigam® (immune globulin intravenous, human), 10% liquid, is also FDA approved for the treatment of PI, but has not been available due to production issues. Launch of Asceniv is anticipated in the second half of 2019.
● Balversa™ (erdafitinib): The FDA granted accelerated approval to Janssen’s Balversa for the once-daily oral treatment of adults with locally advanced or metastatic urothelial carcinoma which has susceptible fibroblast growth factor receptor (FGFR)3 or FGFR2 genetic alterations and who have progressed during or following at least one line of prior platinum-containing chemotherapy. Janssen anticipates the average annual WAC will be approximately $221,000. In addition, the FDA approved Qiagen’s companion diagnostic test to detect the urothelial tumors with FGFR gene alterations.

New indications

● Tecentriq® (atezolizumab): Genentech received FDA approval to expand Tecentriq’s indications to include the first-line treatment of adults with extensive-stage small cell lung cancer in combination with carboplatin and etoposide. Tecentriq is also approved in certain patients with urothelial carcinoma, non-small cell lung cancer, and triple-negative breast cancer.

● Cimzia® (certolizumab pegol): UCB received FDA approval for the treatment of adults with radiographic axial spondyloarthritis (nr-axSpA), with objective signs of inflammation. Cimzia was previously approved for certain patients with Crohn’s disease, rheumatoid arthritis, and plaque psoriasis.

● Ibrance® (palbociclib): Pfizer announced the FDA approval of Ibrance in combination with specific endocrine therapies for hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in male patients. Prior to this approval, it was approved in the same population in women.

● Keytruda® (pembrolizumab): Merck received a revised first-line monotherapy indication for Keytruda which now includes patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation along with metastatic NSCLC patients, the PD-L1 threshold is now set at a tumor proportion score (TPS) of 1% or higher. Previously, Keytruda had been indicated for first-line monotherapy of metastatic NSCLC only in patients with high PD-L1 expression TPS of 50% or higher. In addition, the FDA approved Keytruda for use in combination with Pfizer’s Inlyta® (axitinib) for first-line treatment of advanced renal cell carcinoma.

Specialty generic drug information

● Exjade® (deferasirox): Actavis/Teva launched the first generic for Novartis’ Exjade for the treatment of chronic iron overload due to blood transfusions in certain patients. At least two other generic manufacturers are anticipated to launch their generic version of Exjade in October 2019. U.S. annual sales of Exjade were $134 million in 2018.

● Letairis® (ambrisentan): Sun, Zydus, Par/Endo, and Sigmapharm have launched their generic versions of Gilead Sciences’ Letairis for the treatment of pulmonary arterial hypertension (PAH):
  1. to improve exercise ability and delay clinical worsening, and
  2. in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.

Multiple other manufacturers are expected to launch their generic versions in the second quarter of 2019. Letairis generated $943 million in U.S. annual sales in 2018.
April news

- “A U.S. drug cost-effectiveness group has said that Biogen should cut the price of its already-approved spinal muscular atrophy (SMA) drug, while the $4 – $5 million Novartis is suggesting for an unapproved gene therapy for the disease is excessive.”

- “Evoke Pharma, Inc., a specialty pharmaceutical company focused on treatments for gastrointestinal (GI) diseases, today announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its 505(b)(2) New Drug Application (NDA) for Gimoti™ for the relief of symptoms associated with acute and recurrent diabetic gastroparesis.”

- “Celgene Corporation and Acceleron Pharma Inc. today announced that Celgene has submitted a Biologics License Application (BLA) for luspatercept, an erythroid maturation agent, for the treatment of adult patients with very low to intermediate risk myelodysplastic syndromes (MDS)-associated anemia who have ring sideroblasts and require red blood cell (RBC) transfusions and for the treatment of adult patients with beta-thalassemia-associated anemia who require RBC transfusions.”

- “Europe’s Committee for Medicinal Products for Human Use (CHMP) recommended approval of Bluebird Bio’s lentiglobin gene-therapy product for patients with transfusion-dependent beta-thalassemia. CHMP is the drug-reviewing arm of the European Medicines Agency, which is expected to issue a final decision on approval within the next three months.”

- “AbbVie, a global research and development-based biopharmaceutical company, announced today that Health Canada has approved SKYRIZI™ (risankizumab) for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.”

References