New approvals

- **Jynarque™ (tolvaptan):** The Food and Drug Administration (FDA) approved Otsuka’s Jynarque to slow kidney function decline in adults at risk of rapidly progressing Autosomal Dominant Polycystic Kidney Disease (ADPKD). Jynarque is available through a restricted distribution program and launched as a 28-day treatment pack with a wholesale acquisition cost of $13,031.10. Tolvaptan was first approved in 2009 as Otsuka’s Samsca® for the treatment of clinically significant hypervolemic and euvolemic hyponatremia, including patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH). Samsca may be available as a generic sometime in 2018 – 2019.

- **Retacrit™ (epotin alfa-epbx):** Hospira/Prizer’s Retacrit, the first biosimilar to Procrit®/Epogen® (epotin alfa), was FDA approved for the treatment of anemia due to: chronic kidney disease, zidovudine use in patients with HIV, or myelosuppressive chemotherapy; and for the reduction of allogeneic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery. Retacrit is highly similar to Procrit/Epogen with no clinically meaningful difference between product; however, Retacrit has not been shown to be interchangeable with Procrit/Epogen. A Pfizer representative noted that the launch is planned in 2018 at a significant discount to the WAC price of the reference product.

- **Aimovig™ (erenumab-aooe):** The FDA approved Amgen/Novartis’ Aimovig for the prevention of migraines. Aimovig is a self-administered monthly subcutaneous injection. It launched with an annual WAC of $6,900. Aimovig is the first approval in a new class of monoclonal antibodies (mAb) that target the calcitonin gene-related peptide (CGRP) pathway. Both Eli Lilly (galcanezumab) and Teva (fremanezumab) are anticipating approvals and launches in 2018 in this drug category, both of which are also self-administered subcutaneous injections. Galcanezumab will be administered once monthly; whereas, fremanezumab may be approved for both monthly and quarterly injections. Alder Biopharmaceuticals anticipates FDA approval in 2019 for their oral anti-CGRP eptinezumab for the prevention of migraine.
New approvals (continued)

- **Doptelet™ (avatrombopag):** Dova Pharmaceuticals received FDA approval for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. Patients either take 40 mg or 60 mg of Doptelet orally for 5 days, 10 to 13 days prior to a scheduled procedure.² In clinical trials, Doptelet reduced the number of patients requiring a platelet transfusions when compared with placebo. Doptelet is the first drug approved for this indication, Shinonogi’s lusutrombopag is being reviewed by the FDA for a similar indication with an anticipated approval date of August 26, 2018. Dova plans to file a supplementary New Drug Application (sNDA) for immune thrombocytopenic purpura (ITP) before the end of the year.

New indications

- **Kymriah® (tisagenlecleucel):** Novartis’ Kymriah received FDA approval for adults with relapsed/refractory large B-cell lymphoma after 2 or more line of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. Novartis has set a list price of $373,000 for this indication, the same price of Gilead’s Yescarta (axicabtagene ciloleucel).⁴ Kymriah will continue to be priced at $475,000 in the leukemia market.

- **Tafinlar® (dabrafenib) + Mekinist® (trametinib):** Novartis received FDA approval for Tafinlar and Mekinist administered together as adjuvant treatment for patients with melanoma with BRAF V600E or V600K mutations and involvement of lymph nodes following complete resection. This combination was also approved for patients with BRAF V600E mutation-positive unresectable or metastatic anaplastic thyroid cancer.

- **Darzalex® (daratumumab):** Genmab received FDA approval for Darzalex in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation.

- **Gilenya® (fingolimod):** The FDA approved Gilenya to treat relapsing forms of multiple sclerosis in children and adolescents age 10 years and older.

- **Actemra® (tocilizumab):** Genentech received FDA approval for the Actemra subcutaneous formulation to treat active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older. The intravenous formulation was previously approved for this indication. The subcutaneous formulation is also approved for rheumatoid arthritis and giant cell arteritis.

- **Prolia® (denosumab):** The FDA approved Amgen’s Prolia for the treatment of glucocorticoid-induced osteoporosis (GIOP) in men and women at high risk of fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
May news

- “Akcea Therapeutics announced that the FDA’s Division of Metabolism and Endocrinology Products Committee voted (12 – 8) in favor of Waylivra’s (volanesorsen) approval for the treatment of patients with familial chylomicronemia syndrome (FCS).”

- “Just one dose of a drug called stannsoporfin significantly reduced bilirubin levels in newborns with severe hyperbilirubinemia, but at the potential cost of long-term neurological risk, according to an FDA briefing document prepared for an advisory committee meeting.”

- “Lipocine Inc., a specialty pharmaceutical company, announced today that it has received a Complete Response Letter (CRL) from the FDA regarding its New Drug Application (NDA) for Tlando™, the Company’s oral testosterone product candidate for testosterone replacement therapy (TRT) in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism.”

- “Advisors to the FDA voted 18 – 1 that a new immediate-release sublingual buprenorphine spray should not be approved.”

- “The New England Journal of Medicine (NEJM) published detailed results from two Phase 3 trials for the investigational use of Dupixent® (dupilumab) in moderate-to-severe asthma. The results showed that Dupixent significantly reduced the risk of severe asthma attacks (exacerbations), improved lung function and reduced dependence on oral corticosteroids (OCS). The trials, known as QUEST and VENTURE, are part of the pivotal clinical trial program that evaluated Dupixent in uncontrolled asthma patients.”

- “SIGA Technologies, Inc., a health security company specializing in the development and commercialization of solutions for serious unmet medical needs and biothreats, announced a favorable outcome of the FDA Antimicrobial Drugs Advisory Committee meeting on oral TPOXX®, a small molecule antiviral treatment for smallpox. The panel, comprised of independent medical experts, voted unanimously, 17 to 0, that the benefits of TPOXX outweigh its risks.”

References


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