**Specialty Pipeline Update**

**Drug Insights  October 2016**

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### New approvals

- **Amjevita™ (adalimumab-atto):** The U.S. Food and Drug Administration (FDA) approved Amgen’s Amjevita as a biosimilar to Humira® (adalimumab). Amjevita was approved for seven inflammatory diseases, including moderate-to-severe rheumatoid arthritis, moderate-to-severe polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, moderate-to-severe chronic plaque psoriasis, adult moderate-to-severe Crohn’s disease, and moderate-to-severe ulcerative colitis. Amjevita was not approved for three of Humira’s indications: pediatric Crohn’s disease, hidradenitis suppurativa, and uveitis. Amjevita is approved for patients 4 years or age and older in juvenile idiopathic arthritis, whereas, Humira is approved to treat these patients 2 years of age and older. The earliest possible launch for Amjevita would be March 2017; however, due to patent litigation it may be not be launched until August 2022.

- **Ilaris® (canakinumab):** Novartis’ Ilaris was approved for three rare autoinflammatory diseases known as periodic fever syndromes: Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPSS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), and Familial Mediterranean Fever (FMF) not adequately controlled with colchicine. Prior to the approval of these indications, Ilaris was already approved for Cryopyrin-Associated Periodic Syndromes (CAPS) and Systemic Juvenile Idiopathic Arthritis (SJIA).

- **Tecentriq® (atezolizumab):** Roche’s Tecentriq is now approved for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) patients who have progressed during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Tecentriq. In May, Tecentriq was approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: have disease progression during or following platinum-containing chemotherapy; or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

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### New indications

- **Orkambi® (lumacaftor/ivacaftor):** Vertex Pharmaceutical’s Orkambi is now approved for the treatment of cystic fibrosis in patients 6 years of age and older who are homozygous for the F508del mutation in the CFTR gene. Prior to the approval of this strength, Orkambi was only approved for patients 12 years of age and older.

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October news

- “Pfizer Inc. announced today that the company will begin shipment of INFLECTRA® (infliximab-dyyb) for injection, a biosimilar of REMICADE® (infliximab) to wholesalers in the United States (U.S.) in late November 2016.”

- “Add another stack of data to Sanofi and Regeneron’s stash on blockbuster-to-be dupilumab. The experimental treatment for atopic dermatitis, aka eczema, aced a pair of late-stage studies, presented at the European Academy of Dermatology and Venereology meeting in Vienna. Recently, the drug won priority review from the FDA, putting it on course for a potential launch in March, under the brand name Dupixent™”. As a first-in-class med for patients who are suffering despite other treatments, dupilumab could continue that course right to blockbuster territory.”

- “Rucaparib, binimetinib, and brigatinib undergo FDA scrutiny. Three companies developing cancer therapies are hoping to win nods from the FDA next year. Clovis Oncology, Array BioPharma, and Ariad Pharmaceuticals are all awaiting approval responses, according to a report from BioSpace.”

- “There’s been a considerable amount of chatter over whether or not Kite can expect to win an accelerated FDA approval for its leading CAR-T drug based on 3 months of response data. But the biotech is touting its case at ESMO, hitting hard on positive 12-month results from a tiny study to back up their case that KTE-C19 has a durable impact on chemorefractory, aggressive non-Hodgkin lymphoma patients. The complete remission rate for the drug is 43 percent through a full year of treatment, says Kite.”

- “Maintenance therapy with a PARP inhibitor led to significant prolongation of progression-free survival (PFS) in patients with recurrent, platinum-sensitive ovarian cancer, a large placebo-controlled trial showed. Median PFS approached 2 years in patients treated with niraparib as compared with 5.5 months for placebo-treated patients with germline BRCA mutations. Patients with non-BRCA disease had briefer PFS but still derived a similar magnitude of benefit when treated with the PARP inhibitor. Niraparib-treated patients had higher rates of hematologic toxicity, but that did not lead to discontinuation in most cases, Mansoor R. Mirza, MD, of Rigshospitalet in Copenhagen, reported at the European Society for Medical Oncology conference.”

- “In a 24-week Eli Lilly-sponsored study, selective inhibition of Janus kinase (JAK) 1 and 2 with once-daily oral baricitinib demonstrated superior clinical and structural efficacy compared with placebo in patients with active rheumatoid arthritis (RA) for whom conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) had failed. The 22-country randomized controlled RA-BUILD trial, published in Annals of the Rheumatic Diseases, reported that at week 12, more patients on baricitinib achieved an American College of Rheumatology 20 percent (ACR20) response with baricitinib at 4 mg than with placebo: 62 percent versus 39 percent (P≤0.001). The findings also suggested that a 4 mg dose was more effective than a 2 mg dose.”