New Approvals

- **Reflexis® (infliximab-abda):** Samsung Bioepis/Merck received Food and Drug Administration (FDA) approval for their biosimilar to Johnson & Johnson’s Remicade®, to treat Crohn’s disease, pediatric Crohn’s disease, ulcerative colitis, rheumatoid arthritis in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. There are now two Remicade biosimilars, the first approved was Pfizer/Celltrion’s Inflectra™ (infliximab-dyyb). The launch of Reflexis is not expected until October due to biosimilar rollout rules, but on May 17, 2017 Johnson & Johnson filed a lawsuit to block Reflexis from being sold in the U.S.¹

- **Brineura™ (cerliponase alfa):** The FDA approved BioMarin’s Brineura to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with the orphan disease late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), a type of Batten disease. Brineura is administered by intraventricular infusion with electrolytes over 4.5 hours every other week. BioMarin anticipates a June launch and have reported an annual wholesale acquisition cost (WAC) of $702,000.²

- **Rydapt® (midostaurin):** Novartis received FDA approval for Rydapt, an oral kinase inhibitor for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation positive in combination with standard cytarabine and daunorubicin consolidation. It is also the first approved treatment for the following: aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia.

- **Tymlos™ (abaloparatide):** Radius Health received FDA approval for Tymlos, a daily subcutaneous injection, indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture. Tymlos will compete for market share with Lilly’s Forteo® (teriparatide) which is available generically and Amgen’s Prolia® (desosumab). Radius plans to give Tymlos a WAC of $19,500 annually compared to Forteo’s $35,500.³

- **Imfinzi™ (durvalumab):** The FDA approved AstraZeneca’s Imfinzi for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: have disease progression during or following platinum-containing chemotherapy; or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Imfinzi is administered by intravenous infusion every 2 weeks. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

- **Alunbrig™ (brigatinib):** Ariad Pharmaceuticals received FDA approval for Alunbrig an oral kinase inhibitor for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Pfizer’s Xalkori® (crizotinib). This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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Radicava™ (edaravone): MT Pharma America’s Radicava received FDA approval for the intravenous treatment of amyotrophic lateral sclerosis, also known as Lou Gehrig’s disease. After 6 months of treatment with Radicava, well defined patients with ALS declined less on a clinical assessment of daily functioning compared to patients treated with placebo. Radicava has not been found to be effective in a broader population of ALS patients. MT Pharma America anticipates launch in August 2017 with an annual WAC of $145,524.

Kisqali® (ribociclib) and Femara® (letrozole) Co-Pack: Novartis received FDA approval for Kisqali Femara Co-pack for the oral treatment of hormone receptor-positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer in postmenopausal women. Both Kisqali and Femara are available separately. The Co-Pack is available at the same cost as Kisqali alone.

New indications

- Tecentriq® (atezolizumab): The FDA approved Genetech’s Tecentriq for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: are ineligible for cisplatin chemotherapy; or, have progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.

- Bavencio® (avelumab): Merck/Pfizer’s Bavencio received FDA approval to treat 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.

- Keytruda® (pembrolizumab): Merck’s Keytruda received two new indications:
  - In combination with chemotherapy (permetrexed and carboplatin) for the treatment of patients with previously untreated metastatic nonsquamous non-small cell lung cancer (NSCLC).
  - For the treatment of locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy; or, for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

- Praluent® (alirocumab): The FDA approved Sanofi/Regeneron’s subcutaneous 300 mg once-a-month dose of Praluent for the treatment of adults with high low-density lipoprotein (LDL) cholesterol. The 300 mg dose is administered as two 150 mg injections at two different injection sites.

- Stivarga® (regorafenib): The FDA approved Bayer’s Stivarga for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with Bayer’s Nexavar® (sorafenib).

- Kalydeco® (ivacaftor): Vertex’s Kalydeco received FDA approval to treat additional mutations in the CFTR gene in cystic fibrosis patients age 2 years and older. The approval expands the indication from 10 treatable mutations to 33.

- Actemra® (tocilizumab): Roche’s Actemra received FDA approval to treat patients with giant cell arteritis. This is the first FDA-approved therapy specific to this type of vasculitis.
May news

- “Amgen Inc and UCB SA no longer expect their experimental osteoporosis drug to win U.S. approval this year after a higher rate of serious heart-related side effects were observed in a late-stage clinical trial.”

- “Roche’s Tecentriq® wasn’t supposed to fail its phase 3 trial in second-line bladder cancer. But that’s what it did—and the data shortfall not only endangers the drug’s conditional FDA approval, but could augur trouble ahead for other checkpoint inhibitors that followed Tecentriq into the field.”

- “Pivotal trial results for Merck & Co Inc’s immunotherapy drug Keytruda® show that it lengthened survival by three months, or nearly 40 percent, for patients with advanced bladder cancer who had stopped responding to chemotherapy.”

- “Pfizer announced FDA filing acceptance of supplemental new drug application (sNDA) for Xeljanz® (tofacitinib citrate) for the treatment of adult patients with active psoriatic arthritis. The FDA has provided an anticipated prescription drug user fee act (PDUFA) action date in December 2017.”

- “MT Pharma America, Inc. (MTPA) presented open-label extension data that show patients with amyotrophic lateral sclerosis (ALS) treated with Radicava™ (edaravone) for 48 weeks (12 cycles) experienced significantly less decline in physical function, as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R), compared with patients given placebo for six months followed by six months of Radicava.”

- “A biologics license application has been submitted by Eli Lilly and Co. for its monthly self-administered injection galcanezumab, a monoclonal antibody indicated to treat migraines. The submission was backed by positive data from a late-stage study in which treatment with the drug showed a significantly reduced number of migraine headache days each month.”

References


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