Drug Insights › October 2015

Specialty Pipeline Update

New Drug Information

- **Xuriden™ (uridine triacetate):** In early September, the Food and Drug Administration (FDA) approved Wellstat Therapeutics’ oral therapy for the treatment of hereditary orotic aciduria, a condition that has been reported in approximately 20 patients worldwide.¹ Wellstat has recently submitted for a new indication for patients at risk of serious toxicity following an overdose of the chemotherapy agent 5-fluorouracil (5-FU) and patients exhibiting symptoms of serious toxicity within 96 hours of 5-FU administration. A decision from the FDA is anticipated in March of 2016.

New Indication

- **Opdivo® (nivolumab):** The FDA approved and two additional indications for Opdivo from Bristol-Myers Squibb. The drug is now approved to be used in combination with Yervoy® (ipilimumab) for the treatment of patients with unresectable or metastatic melanoma and for the treatment of patients with metastatic nonsquamous, non-small-cell lung cancer (NSCLC) whose disease progressed during or after platinum-based chemotherapy.

- **Letairis® (ambrisentan):** Gilead Sciences received a broader indication for Letairis. The drug is now indicated for use in combination with tadalafil for the treatment of pulmonary arterial hypertension (WHO Group 1).

October News

- “The U.S. Food and Drug Administration has accepted Novartis unit Sandoz’s regulatory submission for approval of a biosimilar copy of Amgen’s blockbuster Enbrel® drug, the Swiss drugmaker said. Biosimilars aim to copy biologic products, which are made inside living cells, but they can never be exact duplicates, so biosimilar manufacturers need to conduct clinical trials to show their products work as intended... Sandoz is seeking approval for all indications included in the label for Enbrel, a so-called anti-TNF drug, which is used to treat a range of autoimmune diseases including rheumatoid arthritis and psoriasis, it said in a statement.”²

- “An experimental drug has shown promise in treating late-stage multiple sclerosis, reducing annual rates of relapse of major symptoms, its maker reports. The drug ocrelizumab reduced relapses by almost 50 percent compared to an older drug, interferon beta-1a (Rebif®), in three comprehensive clinical trials, its manufacturer Genentech announced.”³

- “U.S. health regulators declined to approve Pfizer Inc’s oral rheumatoid arthritis drug Xeljanz® to treat moderate to severe cases of the scaly skin condition plaque psoriasis, the drugmaker said. Pfizer said it received a so-called complete response letter from the Food and Drug Administration. Such letters typically outline concerns and conditions that must be addressed in order to gain U.S. approval.”⁴

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.
“Eli Lilly and Company and Incyte Corporation announced positive topline results of RA-BEAM, the fourth successful Phase 3 study of baricitinib, an investigational medicine for patients with moderately-to-severely active rheumatoid arthritis. The study met its primary objective of demonstrating superiority compared to placebo after 12 weeks of treatment based on ACR20 response—a standard clinical measure that represents at least a 20 percent improvement in RA disease activity. Baricitinib was also superior to adalimumab on key secondary objectives of ACR20 response and improvement in DAS28-hsCRP score after 12 weeks of treatment. Following 24 weeks of treatment, baricitinib was superior to placebo in preventing progressive radiographic structural joint damage. These treatment benefits with baricitinib observed at 12 and 24 weeks were maintained through 52 weeks of therapy.”

References
1 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm457867.htm
2 http://www.reuters.com/article/2015/10/02/us-novartis-us-idUSKCN0RW0DH20151002
4 http://www.reuters.com/article/2015/10/14/us-pfizer-psoriasis-fda-idUSKCN0SR2QT20151014