February 29, 2016

**Xeljanz XR Approved for Rheumatoid Arthritis**

On Feb. 24, 2016, Pfizer announced that it received U.S. Food and Drug Administration (FDA) approval for Xeljanz® XR (tofacitinib, extended-release) for the treatment of moderate to severe rheumatoid arthritis (RA) in patients who have had an inadequate response or intolerance to methotrexate. The recommended dose of Xeljanz XR is one 11mg tablet once daily. The original formulation of Xeljanz, which is supplied as 5mg tablets, is taken twice daily. Xeljanz is known as a Janus kinase (JAK) inhibitor that has been on the market since November 2012. Full prescribing information can be found at: [http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208246s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208246s000lbl.pdf)

Xeljanz XR will be added to Express Scripts’ specialty drug list.

**New Indication for Ibrance**

On Feb. 19, 2016, FDA approved a new indication for Pfizer’s Ibrance® (palbociclib). It was originally approved about a year ago for use in combination with letrozole to treat postmenopausal women who have advanced breast cancer that is hormone receptor-positive (HR+) and human epidermal growth factor receptor 2-negative (HER2-). The new indication is for the use of Ibrance, in combination with fulvestrant, for treating women of any age who have HR+/HER2- metastatic breast cancer that has progressed despite prior treatment with an endocrine therapy. Premenopausal women being treated also should receive a luteinizing hormone-releasing hormone (LHRH) agonist. Recommended dosing for Ibrance is one 125mg capsule once daily for the first 21 days of each 28-day cycle. For complete prescribing information, please see: [http://www.ibrance.com/](http://www.ibrance.com/)

**Label Expanded for Gazyva**

On Feb. 26, 2016, Genentech announced that FDA approved Gazyva® (obinutuzumab) plus benamustine chemotherapy followed by Gazyva alone for the treatment of patients with follicular lymphoma who did not respond to a Rituxan® (rituximab)-containing regimen, or whose follicular lymphoma returned after such treatment. Gazyva was initially approved in November 2013 for use in combination with chlorambucil chemotherapy for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL). Gazyva is a CD20-directed monoclonal antibody that targets cancer cells directly and with the body’s immune system. It is administered as an intravenous infusion for six (28-day) cycles. Recommended dosing for both indications is 100mg on day one of Cycle 1, 900mg on day two of Cycle 1,
1000mg on days eight and 15 of Cycle 1 and 1000mg on day one of Cycles 2-6. Full prescribing information can be found at:
http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125486s013lbl.pdf

Afinitor Approved for Rare Cancer Types
Novartis’ Afinitor® (everolimus) was approved by FDA on Feb. 26, 2016, for the treatment of adult patients with progressive, non-differentiated, nonfunctional neuroendocrine tumors (NET) of gastrointestinal or lung origin that are unresectable, locally advanced or metastatic. Afinitor is a kinase inhibitor that was first approved in March 2009 for the second-line treatment of advanced renal cell carcinoma (RCC) after failure of treatment with Sutent® (sunitinib - Pfizer) or Nexavar® (sorafenib - Bayer). It has since been approved for several additional cancer types. In May 2011, Afinitor was approved to treat progressive neuroendocrine tumors of pancreatic origin (PNET) that cannot be removed by surgery or that has spread to other parts of the body. The recommended dose to treat neuroendocrine tumors is one 10mg tablet once daily. Full prescribing information can be found at:

Sumatriptan Nasal Spray Approved
Lannett Company, Inc. received FDA approval on Feb. 19, 2016, for sumatriptan nasal spray in 5mg per spray and 20mg per spray strengths. It is a therapeutic equivalent for Imitrex® Nasal Spray. Sumatriptan, a selective 5-HT1B/1D receptor agonist, is indicated to treat adults with acute migraine headaches. Both the brand-name and an authorized generic for sumatriptan nasal spray have been unavailable for the last few months due to unexplained manufacturer delays. Earlier in 2016, FDA approved two new brand sumatriptan products, Onzetra™ Xsail™, a nasally inhaled powdered form of the drug, and Zembrace™ SymTouch™, subcutaneous sumatriptan in a self-injector. Neither has been released for sale, yet; but several oral and injectable forms of sumatriptan are available for treating migraines. According to IMS Health, U.S. sales for all dose forms of Imitrex and sumatriptan amounted to approximately $62 million in 2015. Exact information on launch, prescribing and pricing for Lannett’s generic has not been released, but the company hopes to introduce its sumatriptan nasal spray within the next several months.

New Package Size Approved for Makena
On Feb. 19, 2016, FDA approved a new single-dose vial of Makena® (hydroxyprogesterone 250mg/mL injection - AMAG Pharmaceuticals). Makena is used to prevent early births for women who are pregnant with one fetus and who already have had a pre-term baby (at earlier than 37 weeks of gestation).
It is not indicated for women pregnant with more than one child. The recommended dose is 250mg per week, injected intramuscularly (IM) once a week by a healthcare professional, beginning between weeks 16 and 20, and lasting through week 36 or until birth. Previously, Makena was available only in a multi-dose vial containing five doses and a preservative. Because they are not opened until needed and then discarded after use, the single-dose vials have no preservatives. AMAG plans to introduce them in the second quarter of 2016. Full prescribing information will be available at: http://www.makena.com/

**Higher Strength Aczone Gel**

Allergan’s Aczone® (dapsone) Gel, 7.5% was FDA approved on Feb. 24, 2016. It is applied to clean, dry skin once a day to treat acne in patients at least 12 years old. After three months, treatment options should be re-evaluated if the acne has not improved. Aczone already is available in tubes as a twice-daily 5% gel. The 7.5% gel will be packaged in 30Gm, 60Gm and 90Gm pumps that deliver measured doses of the gel. The manufacturer, Allergan, plans to introduce Aczone 7.5% Gel in May 2016. Pricing has not yet been announced. Prescribing information is at:


**Updated Hepatitis C Issues Document Available**

The standard of care for treating chronic hepatitis C (CHC) is rapidly evolving. The Infectious Diseases Society of America (IDSA) and the American Association for the Study of Liver Diseases (AASLD) in collaboration with the International Antiviral Society-USA (IAS-USA) provides web-based, evidence-based, expert-derived recommendations for hepatitis C management. The guidance is a fluid document, updated as the treatment landscape evolves and new therapies are approved. This Issues Document is intended to describe current and pipeline medications for treating hepatitis C and how Express Scripts and Accredo can effectively manage the evolving market. Click [here](http://origin-gps.onstreammedia.com/origin/multivu_archive/ENR/337672-Allergan-plc.pdf) for the Hepatitis C Issues Document.
Updated DrugWatch Document Available
The Emerging Therapeutics department has updated DrugWatch, a document that highlights near-term pipeline drugs as well as potential new generic opportunities. Click here for the DrugWatch document.