New Approvals

- **Zepatier™ (elbasvir/grazoprevir):** Merck has received Food and Drug Administration approval for their new hepatitis C treatment Zepatier. The drug is approved in adult patients for the treatment of chronic hepatitis C virus (genotypes 1 and 4). Gilead’s Harvoni™ is also approved in both of these genotypes.

New Indications

- **Opdivo® (nivolumab):** Bristol-Myers Squibb’s Opdivo received an additional indication to be used in combination with Yervoy® as a treatment for patients with BRAF V600 wild-type and BRAF V600 mutation-positive unresectable or metastatic melanoma.

- **Botox® (onabotulinumtoxinA):** The FDA approved Allergan’s Botox for the treatment of adults with lower limb spasticity. Botox has been approved for many indications, including upper limb spasticity.

- **Cosentyx® (secukinumab):** Novartis’ Cosentyx was approved by the FDA for two new indications in January. Cosentyx can now be used for the treatment of adult patients with active ankylosing spondylitis (AS) and active psoriatic arthritis (PsA).

- **Halaven® (eribulin mesylate):** The FDA approved Halaven for the second-line treatment of liposarcoma. Halaven was previously approved for the treatment of breast cancer.
January News

- “Lilly and Incyte have filed for U.S. approval of the experimental JAK inhibitor baricitinib as a treatment for moderately-to-severely active rheumatoid arthritis. The drug is the only once-daily oral selective JAK1 and JAK2 inhibitor currently in late-stage clinical studies for inflammatory and autoimmune diseases and so, if approved, would offer patients a new treatment option.”

- “Celltrion is drawing closer to launching its rheumatoid treatment Remsima” in the U.S. The company said that the U.S. Food and Drug Administration is scheduled to hold a committee meeting Feb. 9 to review and discuss Remsima’s approval in the North American market. Remsima is a biosimilar replication of Johnson & Johnson’s blockbuster rheumatoid arthritis treatment Remicade.”

- “U.S. patent officials denied petitions by Amgen to review two formulation patents on AbbVie’s Humira®, a potential setback in Amgen’s efforts to market a biosimilar version of the world’s top-selling prescription medicine. In June, Amgen, the world’s biggest biotechnology company, asked the U.S. Patent and Trademark Office for the review, arguing that the patents in question should not have been granted in the first place for Humira, an injected rheumatoid arthritis treatment with annual sales approaching $14 billion. In declining to review the patents, the agency said ‘we determine, based on the petition and the accompanying evidence, that Amgen has not shown a reasonable likelihood of prevailing on any of its challenges.’ Amgen said it still plans to challenge the legality of the patents.”

References

1 http://www.pharmatimes.com/Article/16-01-19/Lilly_Incyte_file_baricitinib_in_the_US_for_rheumatoid_arthritis.aspx
4 http://www.reuters.com/article/us-amgen-abbvie-humira-idUSKCN0USzWV20160114