New approvals

- **Taltz® (ixekizumab):** The Food and Drug Administration (FDA) approved Lilly’s interleukin 17-A inhibitor for the treatment of moderate to severe plaque psoriasis. Taltz is administered subcutaneously and is similar in mechanism of action to Novartis’ Cosentyx®.

- **Cinqair™ (reslizumab):** Teva received FDA approval for its anti-interleukin-5 monoclonal antibody for the treatment of eosinophilic asthma. Cinqair is an intravenous infusion and is similar in mechanism of action to GlaxoSmithKline’s recently approved Nucala™.

- **Venclexta™ (venetoclax):** AbbVie and Genentech have received FDA approval for their orally administered treatment for chronic lymphocytic leukemia (CLL). Venclexta is indicated for use in CLL patients with the chromosomal abnormality 17p deletion who have been treated with at least one previous therapy.

- **Descovy® (emtricitabine/tenofovir alafenamide):** The FDA approved Gilead’s Descovy for HIV. Descovy is similar to Truvada®, however, it is not approved for pre-exposure prophylaxis.

- **Inflectra™ (infliximab-dyyb):** The FDA approved Celltrion’s biosimilar to Remicade®. Inflectra was approved for rheumatoid arthritis, Crohn’s disease, ulcerative colitis, ankylosing spondylitis, psoriasis and psoriatic arthritis. There is ongoing patent litigation that will likely delay launch to late 2016 or beyond.

- **Defitelio® (defibrotide):** Jazz Pharmaceuticals has received FDA approval for Defitelio for the treatment of hepatic veno-occlusive disease (VOD) following a hematopoietic stem cell transplant (HSCT). Defitelio is administered in the hospital.

New indications

- **Gilotrif™ (afatinib):** Boehringer Ingelheim’s Gilotrif was approved for treatment of patients with advanced squamous cell carcinoma of the lung with progression after first-line chemotherapy. Gilotrif has been previously approved for metastatic NSCLC whose tumors harbor EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.
April news

“An advisory panel to the U.S. Food and Drug Administration unanimously backed the accelerated approval of Intercept Pharmaceuticals Inc’s drug to treat a rare liver condition. The drug, obeticholic acid (OCA), is being reviewed for use in patients with primary biliary cholangitis, a condition in which the body mistakes the bile ducts in the liver as foreign objects and tries to destroy their lining.”

“Hundreds of Duchenne muscular dystrophy activists descended on an FDA panel review of Sarepta’s eteplirsen Monday morning, looking to exert the maximum amount of pressure possible to spur an endorsement from the experts. The initial presentation by the company April 22, including a lengthy defense by interim CEO Edward Kaye of the company’s data from a small study of 12 patients, underscored the deep-seated disconnect between drug investigators and regulators. Eteplirsen, Kaye says, is the first drug to spur a significant increase in dystrophin. Data from the rival drug drisapersen prove that the company’s use of data drawn from historical results is accurate, he added, and there was a clear and dramatic difference in loss of ambulation in the drug arm and the control group used. The FDA’s review disagrees openly with all of these interpretations.”

1 http://www.reuters.com/article/us-intercept-fda-idUSKCN0X42MP
2 http://www.fiercebiotech.com/biotech/sarepta-soars-after-fda-questions-revive-advocates%E2%80%99-hope-for-duchenne-drug?mkt_tok=eyJpIjoiTm1RM1lUVTBNVGhpTkRSbCisInQiOiJwb2doTGlzNzU2RVpyZjmZmJmMymowNUjZjV6SG5tNDZFMGMoRWxVemFVUjM3YKUscLzFqZVhsZHQyOzczNz

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