New approvals

- **Rituxan Hycela™ (rituximab/hyaluronidase human):** The Food and Drug Administration (FDA) approved Genentech and Halozyme Therapeutics’ Rituxan Hycela for subcutaneous injection for the treatment of adults with the following blood cancers: previously untreated and relapsed or refractory follicular lymphoma, previously untreated diffuse large B-cell lymphoma (DLBCL), and previously untreated and previously treated chronic lymphocytic leukemia (CLL). Rituxan Hycela is a co-formulation of the same monoclonal antibody as intravenous (IV) Rituxan® (rituximab) in combination with hyaluronidase human, an enzyme that helps to deliver rituximab under the skin. Rituxan Hycela can be administered in 5 to 7 minutes compared to 1.5 to 4 hours for IV Rituxan. Patients must have received at least 1 full dose of IV Rituxan before Rituxan Hycela may be administered. Rituxan Hycela will launch in either July or August 2017.

- **Haegarda® (CSL830; C1-esterase inhibitor):** The FDA approved CSL Behring’s Haegarda, the first subcutaneous therapy indicated for routine prophylaxis to prevent hereditary angioedema (HAE) attacks in adolescent and adult patients. Haegarda, which is dosed twice weekly, will compete with Shire’s twice weekly intravenous Cinryze® for market share for the HAE prophylaxis indication. Haegarda has launched at a whole acquisition cost (WAC) of about $410,000 annually which represents about a 30 percent discount from Cinryze.

- **Fibryna™ (fibrinogen):** The FDA approved Octapharma’s intravenous Fibryna for the treatment of acute bleeding episodes in adults and adolescents with congenital fibrinogen deficiency, including afibrinogenemia and hypogibrinogenemia. It is not indicated for dysfibrinogenemia.

- **Endari™ (L-glutamine oral powder):** Emmaus Life Sciences received FDA approval for Endari for patients age 5 years and older with sickle cell disease to reduce severe complications associated with the blood disorder. The launch is planned for fourth quarter of 2017 at a reported wholesale acquisition cost of $11,000 – $18,000 annually. L-glutamine powder is available as a prescription product from Emmaus Life sciences as NutreStore® for short bowel syndrome and also is available as a supplement over the counter.
New approvals (continued)

- **Tremfya™ (guselkumab):** Johnson & Johnson received FDA approval for Tremfya to treat adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Tremfya is available as a subcutaneous injection given at Week 0, Week 4 and every 8 weeks thereafter. It may be administered by a health care professional or a patient may self-inject the single-dose prefilled syringe. The wholesale acquisition cost will be around $58,000 annually. This is competitive to the price of other biologic therapies available for psoriasis.¹

- **Nerlynx™ (neratinib):** The FDA approved Puma Biotechnology Inc.’s Nerlynx for the extended adjuvant treatment of early-stage, HER2-positive breast cancer as initial treatment to further lower the risk of the cancer coming back. Nerlynx is indicated for adult patients who have been previously treated with a regimen that includes Herceptin® (trastuzumab). Diarrhea occurs in most patients, they should be given loperamide for the first 56 days of treatment and as needed after that to manage diarrhea. Puma expects to launch Nerlynx in September; pricing has not been released.³,⁶

- **Vosevi™ (sofosbuvir, velpatasvir, voxilaprevir):** Gilead Sciences received FDA approval for Vosevi to treat adults with chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis who have:
  - Genotypes 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor; or
  - Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing Gilead’s Sovaldi® (sofosbuvir) without an NS5A inhibitor.

  Additional benefit of Vosevi over Gilead’s Epclusa® (sofosbuvir/velpatasvir) was not shown in adults with genotype 1b, 2, 4, 5 or 6 infection previously treated with Sovaldi without an NS5A inhibitor. Vosevi was not approved for the initial treatment of HCV infection. Vosevi is a single-tablet regimen taken once daily without ribavirin for 12 weeks.

New indications

- **Tafinlar® (dabrafenib) + Mekinist® (trametinib):** Novartis pharmaceuticals received FDA regular approvals for Tafinlar and Mekinist administered in combination for patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation. These are the first FDA approvals specifically to treat patients with BRAF V600E mutation-positive metastatic NSCLC.

- **Vectibix® (panitumumab):** Amgen’s Vectibix was granted FDA approval for patients with wild-type RAS metastatic colorectal cancer (mCRC) as first-line therapy in combination with FOLFOX and as monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy. Vectibix is the first monoclonal anti-epidermal growth factor receptor (EGFR) antibody approved by the FDA for this patient population.

- **Orencia (abatacept):** The FDA approved Bristol-Myers Squibb’s Orencia for the treatment of adults with active psoriatic arthritis (PsA). This is the third autoimmune disease indication for Orencia.

- **BlinCYTO (blinatumomab):** The FDA converted its accelerated approval for Amgen’s BlinCYTO for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) to a full approval. The prescribing information will now include overall survival data from the Phase 3 TOWER study. The supplemental Biologics License Application (sNDA) also included data from the Phase 2 ALCANTARA study supporting the treatment of patients with Philadelphia chromosome-positive (Ph+) relapsed or refractory B-cell precursor ALL.
July news

- “Novartis announced that the FDA Oncologic Drugs Advisory Committee (ODAC) unanimously (10–0) recommended approval of CTL019 (tisagenlecleucel), an investigational chimeric antigen receptor T cell (CAR-T) therapy, for the treatment of relapsed or refractory (r/r) pediatric and young adult patients with B-cell acute lymphoblastic leukemia (ALL).”
- “Spark Therapeutics, a fully integrated gene therapy company dedicated to challenging the inevitability of genetic disease, announced that the FDA has accepted for filing the Biologics License Application (BLA) and granted Priority Review for voretigene neparvovec, an investigational, potential one-time gene therapy candidate for the treatment of patients with vision loss due to confirmed biallelic RPE65-mediated inherited retinal disease (IRD).”
- “Amgen and UCB announced that the FDA has issued a Complete Response Letter (CRL) for the BLA for Evenity™ (romosozumab) as a treatment for postmenopausal women with osteoporosis.”
- “Pfizer announced that it has received a CRL from the United States (U.S.) FDA regarding the company’s BLA for its proposed epoetin alfa biosimilar.”
- “Coherus BioSciences, Inc., announced that the FDA has issued a CRL for its BLA for CHS-1701, a pegfilgrastim (Neulasta®) biosimilar candidate, under the 351(k) pathway.”
- “Despite struggling with extrapolation, the FDA’s Oncologic Drugs Advisory Committee (ODAC) unanimously supported approval of two biosimilars, referencing Roche Holding AG’s Avastin and Herceptin.”

References


All brand names are property of their respective owners.