New approvals

- **Idhifa™ (enasidenib):** The U.S. Food and Drug Administration (FDA) approved Celgene/Agios Idhifa to treat adults with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test. This specific type of AML represents between 8 to 19% of AML patients.¹ The wholesale acquisition cost (WAC) is $24,872 per month.²

- **Nityr™ (nitisinone):** Cycle Pharmaceuticals received FDA approval for Nityr tablets for the treatment of Hereditary Tyrosinemia type-1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. Nityr is bioequivalent to Orfadin® (nitisinone) capsules. Orfadin is also available as a suspension. Nityr does not need to be refrigerated; Orfadin capsules may be kept at room temperature for up to 45 days and the suspension for up to 60 days.

- **Vyxeos™ (cytarabine and daunorubicin liposome):** Jazz Pharmaceuticals received FDA approval for Vyxeos, a liposomal combination of daunorubicin and cytarabine indicated for the treatment of adults with newly diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC). In a clinical trial, Vyxeos demonstrated superiority in overall survival compared to a standard combination of cytarabine and daunorubicin in patients 60–75 years of age with newly diagnosed t-AML or AML-MRC.³

- **Mavyret™ (glecaprevir/pibrentasvir):** AbbVie received FDA approval for Mavyret for the treatment of patients with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). Mavyret is the first HCV drug with a treatment duration of 8 weeks regardless of genotype. It is also indicated for the treatment of adult patients with HCV genotype 1 infection who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. Mavyret's WAC is $26,400 per treatment course for most patients, which is lower than other available treatment courses such as Gilead’s Sovaldi and Harvoni.⁴

- **Besponsa™ (inotuzumab ozogamicin):** The FDA approved Pfizer’s Besponsa for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) given via intravenous infusion. The National Cancer Institute estimates 5,970 people in the US will be diagnosed with ALL this year and approximately 1,440 will die from the disease.
New indications

- **Benlysta® (belimumab):** GlaxoSmithKline received FDA approval for a subcutaneous formulation of Benlysta for the treatment of adults with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy. Benlysta is the first subcutaneous self-injection treatment option for patients with SLE.

- **Opdivo® (nivolumab):** Bristol Myers Squibb received accelerated approval for Opdivo for the treatment of adult patients with classical Hodgkin Lymphoma (cHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or 3 or more lines of systemic therapy that includes autologous HSCT. Opdivo also received accelerated approval for the treatment of patients 12 years and older with mismatch repair deficient (dMMR) and microsatellite instability high (MSI-H) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

- **Abilify Maintena® (aripiprazole extended-release injectable suspension):** Otsuka/Lundbeck received FDA approval for Abilify Maintena for the maintenance monotherapy treatment of bipolar I disorder in adults. Prior to this approval, Abilify Maintena was approved in the US for the treatment of adults with schizophrenia.

- **Kalydeco® (ivacaftor):** Vertex Pharmaceuticals received FDA approval for Kalydeco for the treatment of cystic fibrosis in patients 2 years and older with one of five splice mutations in the CFTR gene.

- **Imbruvica® (ibrutinib):** AbbVie/Janssen's Imbruvica received FDA approval for the treatment of adult patients with chronic graft-versus-host-disease (cGVHD) after failure of 1 or more lines of systemic therapy. Imbruvica is the first FDA-approved medication for the treatment of cGVHD.

- **Epclusa® (sofosbuvir/valpatasvir):** Gilead's Epclusa received FDA approval to expand use to include patients co-infected with HIV. The drug was previously approved for adult patients with genotype 1 – 6 chronic HCV infection without cirrhosis or with compensated cirrhosis, or with decompensated cirrhosis in combination with ribavirin.

- **Lynparza® (olaparib):** AstraZeneca’s Lynparza tablets, a new formulation, received approval for the maintenance treatment of adult patients with recurrent, epithelial ovarian, fallopian tube or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy, regardless of BRCA status. Also, Lynparza tablets are now indicated (conversion from accelerated approval) for use in adult patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with 3 or more prior lines of chemotherapy. The tablets and capsules are not interchangeable. Lynparza capsules are being phased out of the U.S. market.
August news

● “The National Institute of Healthcare and Excellence (NICE) is set to reject Pfizer’s orphan drug for leukemia Besponsa (inotuzumab ozogamicin). Pfizer issued a robust defense of its product, saying the UK cost-effectiveness watchdog’s final appraisal determination had ‘inappropriately’ assessed the drug’s value.”⁵

● “Gilead Sciences, Inc. announced that the FDA has granted priority review for the company’s New Drug Application (NDA) for an investigational, fixed-dose combination of bictegravir (50mg) (BIC), a novel investigational integrase strand transfer inhibitor (INSTI), and emtricitabine/tenofovir alafenamide (200/25mg) (FTC/TAF), a dual-NRTI backbone, for the treatment of HIV-1 infection. Gilead filed the NDA for BIC/FTC/TAF with a Priority Review voucher on June 12, 2017, and FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of February 12, 2018.”⁶

● “Portola Pharmaceuticals Inc. announced that on August 3, 2017 it resubmitted its Biologics License Application (BLA) to the Center for Biologics Evaluation and Research (CBER) FDA for AndexXa® (andexanet alfa), a reversal agent for Factor Xa inhibitors. The resubmission includes supplemental information primarily related to manufacturing, as requested by the FDA in a complete response letter (CRL) issued to Portola in August 2016.”⁷

● “For years, the foundations of cancer treatment were surgery, chemotherapy, and radiation therapy. Over the last two decades, targeted therapies like imatinib (Gleevec®) and trastuzumab (Herceptin®)—drugs that target cancer cells by homing in on specific molecular changes seen primarily in those cells—have also cemented themselves as standard treatments for many cancers. But over the past several years, immunotherapy—therapies that enlist and strengthen the power of a patient’s immune system to attack tumors—has emerged as what many in the cancer community now call the ‘fifth pillar’ of cancer treatment.”⁸

References


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