New approvals

- No approvals.

New indications

- **Cabometyx® (cabozantinib):** The Food and Drug Administration (FDA) expanded the approval of Exelixis' Cabometyx for the treatment of patients with previously untreated advanced renal cell carcinoma (aRCC). Previously, Cabometyx was approved for aRCC patients who have received prior antiangiogenic therapy.

- **Bosulif® (bosutinib):** The FDA granted accelerated approval to Pfizer’s Bosulif for use in the treatment of adult patients with newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML). Continued approval for this indication may be contingent upon verification and confirmation of clinical benefit in an ongoing long-term follow up trial. Bosulif was first approved for Ph+ CML with resistance or intolerance to prior therapy.

- **Perjeta® (pertuzumab):** Genentech received FDA approval for Perjeta, in combination with Genentech’s Herceptin® (trastuzumab) and chemotherapy, for adjuvant treatment of HER2-positive early breast cancer at high risk of recurrence. Also, the FDA converted the accelerated approval to full approval for a Perjeta-based regimen in the neoadjuvant treatment of HER2-positive, locally advanced, inflammatory, or early stage breast cancer.

- **Procysbi® (cysteamine bitartrate):** Horizon Pharma received expanded FDA approval for use of Procysbi to patients as young as 1 year old with nephropathic cystinosis. Prior to this approval, Procysbi was approved in adult and pediatric patients 2 years of age and older.

- **Xgeva® (denosumab):** The FDA expanded the approval of Amgen’s Xgeva for the prevention of skeletal-related events (SREs) in patients with multiple myeloma. Xgeva was first approved for the prevention of skeletal-related events in patients with bone metastases from solid tumors only.
New indications (continued)

- **Lynparza® (olaparib):** The FDA approved a new indication for AstraZeneca/Merck’s Lynparza in patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment. This is the first FDA approval for metastatic breast cancer patients who have a BRCA gene mutation.¹

- **Trisenox® (arsenic trioxide):** Teva received expanded approval for Trisenox in combination with tretinoin in adult patients with newly diagnosed low-risk acute promyelocytic leukemia (APL) characterized by the presence of (15;17) translocation or PML/RAR-alpha gene expression. Prior to this approval, Trisenox was only approved in the relapsed or refractory APL.

- **Gilotrif® (afatinib):** The FDA expanded the indication of Boehringer Ingelheim’s Gilotrif for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. Safety and efficacy were not established in patients whose tumors have resistant EGFR mutations.

January news

- “The $850,000 list price for a new medicine that treats a genetic form of childhood blindness is about four times too high for the value the drug provides, a nonprofit that studies the cost-effectiveness of new drugs said, though it added that the price of the drug is cost-effective for select patients and with certain assumptions.”²

- “Scientific progress and new drug innovation don’t take place in a vacuum. The exchange of information that informs decisions to undertake research, invest in new scientific endeavors, and prescribe and use certain treatments effectively are a critical part of enabling the development and dissemination of new medical technology. Transparency related to this information can play a critical role in maximizing the public health value of the resulting innovations.”³

- “Pharming Group N.V. announced that the FDA has accepted for review Pharming’s supplemental Biologics License Application (sBLA) for Ruconest® (recombinant C1 esterase inhibitor) for routine prophylaxis to prevent attacks in adult and adolescent patients with hereditary angioedema (HAE). The FDA has indicated that the sBLA is sufficiently complete to permit a substantive review and has set an action date of September 21, 2018.”⁴

- “Sandoz announced that the FDA has accepted its Biologics License Application (BLA) for the proposed biosimilar adalimumab to the reference medicine, Humira, developed by AbbVie, Inc.”⁵

- “Braeburn Pharmaceuticals Inc. said that the FDA issued a complete response letter for its monthly buprenorphine injection depot CAM2038 to treat opioid use disorder. The company said that FDA requested additional data, but further clinical trials are not needed. Braeburn declined further comment.”⁶

- “Aradigm Corporation announced that the Antimicrobial Drugs Advisory Committee (ADAC) of the FDA did not recommend approval for Linhaliq™ as a treatment for non-cystic fibrosis bronchiectasis (NCFBE) patients with chronic lung *Pseudomonas aeruginosa* infections.”⁷

References


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