New drug information

- **Hyrimoz™ (adalimumab):** The Food and Drug Administration (FDA) approved Sandoz Pharmaceuticals’ Hyrimoz for treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn’s disease, ulcerative colitis, and plaque psoriasis. Hyrimoz is a biosimilar for Abbvie’s Humira®. Sandoz reached a settlement with AbbVie that allows Hyrimoz to launch in the United States on Sept. 30, 2023.¹

- **Udenyca™ (pegfilgrastim-cbqv):** The FDA approved Coherus’ Udenyca, to treat cancer patients receiving myelosuppressive chemotherapy. Udenyca is a biosimilar to Amgen’s Neulasta®. Udenyca is the second Neulasta biosimilar joining Mylan’s Fulphila. The WAC price for Udenyca will match that of Mylan’s Fulphila — $4,175 per vial, a 33 percent discount from Neulasta.²

- **Lorbrena™ (lorlatinib):** The FDA approved Pfizer’s lung-cancer treatment for patients with a specific gene mutation who had been previously treated for an aggressive form of the disease. Lorbrena is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on:
  → crizotinib and at least one other ALK inhibitor for metastatic disease; or
  → alectinib as the first ALK inhibitor therapy for metastatic disease; or
  → ceritinib as the first ALK inhibitor therapy for metastatic disease.
Alunbrig® (brigatinib), Zykadia® (ceritinib) and Alecensa® (alectinib) are similar medicines that are also used for treatment of ALK-positive NSCLC.
New indications

- **Avastin® (bevacizumab):** The FDA expanded Roche’s Avastin indications to include treatment in combination with the chemotherapy agents, carboplatin and paclitaxel, followed by Avastin alone, for the first-line treatment of women with advanced ovarian cancer. Avastin was initially approved for the treatment of metastatic colorectal cancer, in combination with intravenous 5-fluorouracil-based chemotherapy for first- or second-line treatment, and for treatment of metastatic colorectal cancer, in combination with fluoropyrimidine irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line Avastin-containing regimen.

- **Praluent® (alirocumab):** The FDA expanded Regeneron’s Praluent for use in combination with apheresis in treatment of adults with heterozygous hypercholesterolemia (HeFH) for clinical ASCVD, who require additional LDL cholesterol lowering.

- **Xyrem® (sodium oxybate) oral solution:** The FDA expanded Jazz Pharmaceuticals’ Xyrem to treat cataplexy and excessive daytime sleepiness (EDS) in pediatric narcolepsy patients aged seven years and older. Xyrem oral solution was initially approved for the treatment of cataplexy in patients with narcolepsy.

- **Keytruda® (pembrolizumab):** The FDA expanded Merck’s Keytruda for use in combination with carboplatin-paclitaxel or nab-paclitaxel (Abraxane) chemotherapy for the first-line treatment of squamous metastatic non-small cell lung cancer (NSCLC). Keytruda was initially approved for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor.

- **Empliciti® (elotuzumab):** The FDA expanded Bristol-Myers Squibb’s Empliciti in combination with Celgene’s Pomalyst® (pomalidomide) and low-dose dexamethasone, to treat patients with relapsed/refractory multiple myeloma (MM) who have received at least two prior lines of therapy. It was initially approved in combination with lenalidomide and dexamethasone for the treatment of patients with MM who have received one to three prior therapies.

- **Adcetris® (brentuximab vedotin):** The FDA expanded the use of Seattle Genetics’ Adcetris in combination with chemotherapy for adult patients with certain types of peripheral T-cell lymphoma (PTCL). This is the first FDA approval for treatment of newly diagnosed PTCL.

- **Promacta® (eltrombopag):** Novartis received FDA approval for Promacta to be used as first-line treatment of severe aplastic anemia in patients at least two years old, in combination with standard immunosuppressive therapy.
November news

● “Novartis said its Sandoz division is abandoning an effort to gain U.S. regulatory approval for a biosimilar of rituximab, a medication used to treat certain cancers and rheumatoid arthritis. The decision comes after the Food and Drug Administration (FDA) sought additional information to support the company’s application for the drug. Rituximab is a biosimilar drug referencing a Roche medication marketed as Rituxan® in the United States and elsewhere.”

● “Japan’s Chugai Pharmaceutical has filed a patent infringement lawsuit against Alexion Pharmaceuticals in the U.S. District Court for Delaware. Chugai alleges that the anti-C5 antibody ALXN1210 (ravulizumab) infringes one of its U.S. patents, relating to its proprietary antibody engineering technology.”

● “The FDA has given priority review status to Roche Holding’s Tecentriq® in combination with chemotherapy Abraxane as an initial treatment for patients with metastatic triple-negative breast cancer whose tumor is PD-L1 positive. The agency is expected to make a decision by March 12.”

● “The FDA has accepted AstraZeneca and Merck’s application for Lynparza®, or olaparib, under priority review. The drug is being developed as a maintenance therapy for patients with newly diagnosed BRCA mutation-positive advanced ovarian cancer who are in complete or partial response after first-line platinum-based chemotherapy.”

● “Novartis may put a $4 million to $5 million price tag on its ‘one-time, potentially curative’ gene therapy AVXS-101 for spinal muscular atrophy (SMA) and believes this could be cost-effective. Novartis bases its cost-effectiveness model on a 10-year cost of treatment set against quality-adjusted life years (QALY) gained. At a $4 million list price, QALY for AVXS-101 is 13.3, which is within the range for lifelong therapies for rare diseases, including Spinraza® (nusinersen, by Biogen), according to Novartis. Spinraza—the first approved SMA treatment—carries a list price of $750,000 for the first year and about $375,000 for subsequent years, which amounts to around $4.1 million per patient over 10 years.”

● “Pfizer announced the introduction of Retacrit®, its epoetin alfa biosimilar, which is indicated to treat various forms of anemia. Pfizer is offering Retacrit at a significant discount to Amgen’s Epogen® and Johnson & Johnson’s Procrit®. Pfizer started shipping Retacrit to wholesalers at a list price that is 57 percent discount to Procrit and a 33.5 percent discount to Epogen.”

References


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