New approvals

- **Ilumya™ (tildrakizumab-asmn):** The Food and Drug Administration (FDA) approved Sun Pharmaceutical Industries’ Ilumya for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Ilumya is administered by subcutaneous injection that should only be administered by a health care provider. Ilumya is similar in mechanism of action to J & J’s Tremfya®. Tremfya has an at-home dosing option and is dosed every 2 months after a loading dose. After loading doses, Ilumya is dosed every 3 months.

- **Crysvita® (burosumab-twza):** Ultragenyx and Kyowa Kirin received FDA approval for Crysvita for the treatment of adults and children aged 1 year and older with X-linked hypophosphatemia, a rare, inherited form of rickets. Crysvita is administered by subcutaneous injection and should be administered by a health care provider. Using the average maximum dose a child or an adult would receive, the annual wholesale acquisition cost (WAC) is approximately $375,000 annually. Ultragenyx plans to launch in early May.¹

- **Tavalisse™ (fostamatinib disodium hexahydrate):** The FDA approved Rigel’s Tavalisse for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. Tavalisse is the first oral spleen tyrosine kinase (SYK) inhibitor with launch anticipated in late May.²
New indications

- **Adcetris® (brentuximab vedotin):** Seattle Genetics’ Adcetris received FDA approval for the treatment of adult patients with previously untreated stage III or IV classical Hodgkin lymphoma in combination with chemotherapy.

- **Tasigna® (nilotinib):** The FDA approved the use of Novartis’ Tasigna in the treatment of newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in pediatric patients 1 year or older that is in chronic phase (Ph+ CML-CP) or Ph+ CML-CP-resistant or is intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.

- **Blincyto® (blinatumomab):** Amgen received FDA accelerated approval for Blincyto to treat adults and children with B-cell precursor acute lymphoblastic leukemia (ALL) who are in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. MRD is the presence of cancer cells below a level that can be seen under the microscope. Continued approval may be contingent upon verification and description of clinical benefit in the confirmatory trials. Blincyto is also approved for the treatment of relapsed or refractory B-cell precursor ALL.

- **Leukine® (sargramostim):** The FDA approved Leukine to increase survival in adult and pediatric patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome, or H-ARS). Leukine is the third FDA-approved medical countermeasure with this indication.

- **Rubraca® (rucaparib):** The FDA approved Clovis Oncology’s Rubraca for the maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. This is a broader and earlier-line indication than Rubraca’s first approval for adult patients with deleterious BRCA mutation-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 2 or more chemotherapies.

- **Opdivo® (nivolumab) + Yervoy® (ipilimumab):** Bristol-Myers Squibb received FDA approval for the use of Opdivo in combination with Yervoy for the treatment of intermediate or poor risk, previously untreated advanced renal cell carcinoma.

- **Vonvendi® [von Willebrand factor (recombinant)]:** The FDA approved Shire’s Vonvendi for perioperative management of bleeding in adult patients with von Willebrand disease. Vonvendi is also indicated for on-demand treatment and control of bleeding episodes.

- **Tagrisso® (osimertinib):** Aerie Pharmaceuticals received FDA approval for Tagrisso for first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations. Prior to this approval, Tagrisso was approved for patients with EGFR T790M-positive NSCLC whose disease progressed on or after EGFR TKI therapy.
April news

- “GW Pharma’s cannabis-based epilepsy treatment inched one step closer to FDA approval. In a 13-0 vote, an expert panel decided that the risk-benefit profil the first cannabis-based prescription med in the U.S.”
- “Celltrion has received coe of Epidiolex is favorable for the treatment of seizures stemming from two rare forms of epilepsy. It is on track to becomemplete response letters (CRLs) from the FDA for two biologics license applications (BLAs) for rituximab and trastuzumab biosimilars.”
- “Pfizer reported that it received a CRL from the FDA in response to the BLA for the company’s proposed trastuzumab biosimilar. In the CRL, the FDA highlighted the need for additional technical information.”
- “In a swift about-face, the FDA has chosen to accept Alkermes plc’s New Drug Application for its major depressive disorder drug ALKS-5461.”
- “Novartis announced new analyses from the Phase III EXPAND study of oral, once-daily siponimod (BAF312) in patients with secondary progressive multiple sclerosis (SPMS). In pre-specified statistical analyses, treatment with siponimod consistently reduced the risk of confirmed disability progression in SPMS patients, with and without relapses.”
- “An arthritis drug developed by Eli Lilly & Co and Incyte Corp should not be approved at a 4-milligram dose, advisers to the FDA voted, in a setback to the drugmakers that were counting on the treatment as a future blockbuster.”

References


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