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Approved Drugs

• On August 11, the US Food and Drug Administration (FDA) approved the fixed dose combination of **Akeega™ (niraparib and abiraterone acetate)** (Janssen, janssen.com), **in combination with prednisone**, for adult patients with deleterious or suspected deleterious BRCA-mutated castration-resistant prostate cancer, as determined by an FDA-approved test.

• On June 15, the FDA granted accelerated approval to **Columvi® glofitamab-gxbm** (Genentech, Inc., gene.com) for relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified or large B-cell lymphoma arising from follicular lymphoma, after 2 or more lines of systemic therapy.

• On August 14, the FDA granted accelerated approval to **Elrexfio® (elranatamab-bcmm)** (Pfizer, Inc., pfizer.com) for adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

• On August 9, the FDA approved **Gavreto® (pralsetinib)** (Genentech, gene.com) for adult patients with metastatic rearranged during transfection fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

• On August 14, the FDA approved **Hepzato® (melphalan)** (Delcath Systems, Inc., delcath.com) as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extra-hepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation.

• On July 31, the FDA approved **Jemperli® (dostarlimab-gxly)** (GSK, gsk.com) **in combination with carboplatin and paclitaxel** followed by single-agent **dostarlimab-gxly** for primary advanced or recurrent endometrial cancer that is mismatch repair deficient, as determined by an FDA-approved test, or microsatellite instability-high.

• On August 2, the FDA approved **Lonsurf® (trifluridine and tipiracil)** (Taiho Oncology, Inc., taihooncology.com) **in combination with bevacizumab**, for metastatic colorectal cancer previously treated with fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.

• On June 20, the FDA approved **Talzenna® (talazoparib)** (Pfizer, Inc., pfizer.com) **in combination with enzalutamide** for homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer.

• On August 9, the FDA granted accelerated approval to **Talvey® (talquetamab-tgvs)** (Janssen, janssen.com), for adults with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

• On July 20, the FDA approved **Vanflyta® (quizartinib)** (Daiichi Sankyo, Inc., daiichisankyo.com) with standard **cytarabine and anthracycline induction and cytarabine consolidation**, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia that is FLT3 internal tandem duplication-positive, as detected by an FDA-approved test.

Drugs In the News

• BeiGene (beigene.com), announced the FDA has granted a supplemental new drug application (NDA) for **Brukinsa® (zanubrutinib) in combination with obinutuzumab** for the treatment of adult patients with relapsed or refractory follicular lymphoma after at least 2 prior lines of therapy.

• Actuate Therapeutics, Inc. (actuate-therapeutics.com) announced that the FDA has granted orphan drug designation for **elraglusib** for treatment of patients with pancreatic cancer.

• Geron Corporation (geron.com) announced the submission of an NDA to the FDA for **imetelstat** for the treatment of transfusion-dependent anemia in adult patients.

- GSK (gsk.com) announced that the FDA has extended the review period of the NDA for **momelotinib** by 3 months to provide time to review recently submitted data. The extended action date is 16 September 2023.

- Ipsen (Ipsen.com) announced that the FDA has accepted its supplemental NDA for **Onivyde® (irinotecan liposome injection)** plus 5 **fluorouracil/leucovorin and oxaliplatin** as a potential first-line treatment for metastatic pancreatic ductal adenocarcinoma.

- Kazia Therapeutics Limited (kaziatherapeutics.com) announced the FDA granted fast track designation to **paxalisib** for the treatment of solid tumor brain metastases harboring PI3K pathway mutations in combination with radiation therapy.

- Genprex, Inc. (genprex.com) announced that the FDA has granted fast track designation to **Reqorsa®** immunogene therapy, in combination with Genentech's (gene.com) **Tecentriq®** in patients with extensive-stage small cell lung cancer who did not develop tumor progression after receiving Tecentriq and chemotherapy as initial standard treatment.

- Elevar Therapeutics (elevartherapeutics.com) announced that the FDA accepted an NDA for **rivoceranib in combination with camrelizumab** as a first-line treatment option for unresectable hepatocellular carcinoma.

- Servier (Servier.com) announced the FDA has accepted a supplemental NDA and granted priority review for **Tibsovo® (ivosidenib tablets)** in the treatment of patients with isocitrate dehydrogenase 1 (IDH1)-mutated relapsed or refractory myelodysplastic syndromes.

- Merus N.V. (www.merus.nl) announced that the FDA has granted breakthrough therapy designation for **zenocutuzumab** for the treatment of patients with advanced unresectable or metastatic NRG1 fusion (NRG1+) pancreatic cancer following progression with prior systemic therapy or who have no satisfactory alternative treatment options.

- Astellas Pharma Inc. (astellas.com) announced that the FDA has accepted and granted priority review for the company's biologics license application (BLA) for **zolbetuximab**, for first-line treatment of patients with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are Claudin 18.2-positive.

Approved Diagnostic Tests and Assays

- On August 14, the FDA approved **FoundationOne®CDx** (Foundation Medicine, foundationmedicine.com) to be used as a companion diagnostic for **Akeega™** (niraparib and abiraterone acetate) (Janssen, janssen.com), which was approved by the FDA for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated castration-resistant prostate cancer.