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Approved Drugs

• The Food and Drug Administration (FDA) has approved Pfizer's (Pfizer.com) **Besponsa® (inotuzumab ozogamicin)** for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

• Amgen (amgen.com) announced that the FDA has approved the supplemental biologics license application (sBLA) for **Blincyto® (blinatumomab)** to include overall survival (OS) data from the Phase III TOWER study. The approval converts the drug's accelerated approval to a full approval. The sBLA approval also included data from the Phase II ALCANTARA study supporting the treatment of patients with Philadelphia chromosome-positive (Ph+) relapsed or refractory B-cell precursor ALL. The approval expands the indication of Blincyto for the treatment of relapsed or refractory B-cell precursor ALL in adults and children.

• Celgene Corporation (celgene.com) and Agios Pharmaceuticals, Inc. (agios.com) announced that **Idhifa® (enasidenib)** was granted FDA approval for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (R/R AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as directed by an FDA-approved test.

• The FDA approved **Imbruvica® (ibrutinib)** (Pharmacyclics LLC, pharmacyclics.com) for the treatment of adult patients with chronic graft versus host disease after failure of one or more lines of systemic therapy.

• The FDA approved **Nerlynx™ (neratinib)** (Puma Biotechnology, Inc., pumabiotechnology.com) for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab-based therapy.

• Bristol-Myers Squibb Company (bms.com) announced that the FDA has approved **Opdivo® (nivolumab)** injection for intravenous use for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

• The FDA has approved a combination of Genentech's (gene.com) **Rituxan® (rituximab)** and Halozyme Therapeutics, Inc.'s (halozyme.com), hyaluronidase human enzyme **Enhaze™ drug delivery** technology for subcutaneous injection in multiple blood cancer indications.

• Novartis (novartis.com) announced FDA approval of **Tafinlar® (dabrafenib)** in combination with **Mekinist® (trametinib)** to treat patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express the BRAF V600E mutation.

• The FDA approved **Vyxeos™ (cytarabine and daunorubicin)** (Jazz Pharmaceuticals, jazzpharma.com) for the treatment of adults with two types of acute myeloid leukemia (AML): newly-diagnosed therapy -related AML or AML with myelodysplasia-related changes.

• Bristol-Myers Squibb Company (bms.com) announced that the FDA has expanded the indication for **Yervoy® (ipilimumab)** injection for intravenous use to now include the treatment of unresectable or metastatic melanoma in pediatric patients 12 years of age and older.

Approved Devices

• The FDA cleared the expanded use of a cooling cap, **DigniCap® Cooling System** (Dignitana, Inc., dignitana.se), to reduce hair loss during chemotherapy.

• Varian Medical Systems (varian.com) has received FDA 510(k) clearance for its **Halcyon™** system.

• Royal Philips (philips.com) announced it has received 510(k) clearance from the FDA to market **IntelliSpace Portal 9.0** and a range of radiology applications for longitudinal brain imaging multi-modality tumor tracking and lung nodule assessment.

• The FDA has granted premarket approval to Thermo Fisher Scientific, Inc. (thermofisher.com) for its **Oncomine Dx Target Test**, a next-generation sequencing (NGS)-based test that simultaneously screens tumor samples for biomarkers associated with three FDA-approved

therapies for NSCLC. Following FDA approval, results from analysis of three of these genes can be used to identify patients who may be eligible for treatment with one of the following: the combined therapy of **Tafinlar® (dabrafenib)** and **Mekinist® (trametinib)**, **Xalkori® (crizotinib**), or **Iressa® (gefitinib)**.

Drugs in the News

• Eli Lilly and Company (lilly.com) announced that the FDA has accepted and filed its new drug application (NDA) for **abemaciclib**, a cyclin-dependent kinase (CDK)4 & 6 inhibitor, and given the NDA a priority review designation. The NDA includes the company's submission of abemaciclib for two indications: abemaciclib monotherapy for patients with hormone-receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer who had prior endocrine therapy and chemotherapy for metastatic disease; and for abemaciclib in combination with fulvestrant in women with HR+ HER2- advanced breast cancer who had disease progression following endocrine therapy.

• Amgen (amgen.com) and Allergan (allergan.com) announced the submission of a BLA to the FDA for **ABP 980**, a biosimilar candidate to Herceptin® (trastuzumab).

• AstraZeneca (astrazeneca.com) announced that the FDA has granted breakthrough designation to **acalabrutinib (ACP-196)** for the treatment of patients with mantle cell lymphoma.

• Genentech (gene.com) announced that the FDA has accepted the company's supplemental NDA and granted priority review for **Alecensa® (alectinib)** as first-line treatment for people with anaplastic lymphoma kinase (ALK)-positive, locally advanced or metastatic NSCLC as detected by an FDA-approved test.

• Astellas Pharma, Inc. (astellas.com) announced that the FDA has granted orphan-drug designation to **gilteritinib (ASP2215)** for patients with AML.

• AstraZeneca (astrazeneca.com) announced that the FDA has granted breakthrough therapy designation for **Imfinzi™ (durvalumab)** for the treatment of patients with locally-advanced unresectable NSCLC whose disease has not progressed following platinum-based chemoradiation therapy.

• Eisai, Inc. (eisai.com) has submitted a supplemental NDA to the FDA for the first-line use of **Lenvima® (lenvatinib)** in patients with hepatocellular carcinoma.

• Bristol-Myers Squibb (bms.com) announced that the FDA has accepted its sBLA to update **Opdivo® (nivolumab)** dosing to include 480 mg infused over 30 minutes every four weeks for all currently approved monotherapy indications.

• Bristol-Myers Squibb Company (bms.com) announced that the FDA accepted its sNDA to include an indication for **Sprycel® (dasatinib)** to treat children with Philadelphia chromosome-positive chronic phase chronic myeloid leukemia (CML), as well as a powder for oral suspension formulation of Sprycel.

• The FDA has awarded orphan drug designation to MimiVax LLC (mimivax.com) for its vaccine, **SurVaxM**, for the treatment of glioblastoma.

• Syros Pharmaceuticals (syros.com), announced that the FDA has granted orphan drug designation to **SY-1425**, an oral selective retinoic acid receptor alpha (RARα) agonist, for the treatment of AML.

• Amgen (amgen.com) announced that the FDA has approved the sBLA for **Vectibix® (panitumumab)** for patients with wild-type RAS (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use) metastatic colorectal cancer as first-line therapy in combination with FOLFOX and as monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy. As part of this new indication, the FDA approved the first multigene, NGS-based test to identify the RAS mutation status of a patient's tumor.

• Roche (roche.com) announced that the FDA has granted breakthrough therapy designation for **Venclexta® (venetoclax)** in combination with low dose cytarabine for elderly patients with previously untreated AML who are ineligible for intensive chemotherapy.

Genetic Tests and Assays in the News

• The FDA authorized the marketing of Clear Lab Reagents **(T1, T2, B1, B2, M)** test to aid in the detection of several leukemias and lymphomas, including chronic leukemia, acute leukemia, non-Hodgkin lymphoma, myeloma, myelodysplastic syndrome (MDS), and myeloproliferative neoplasms (MPN).

• The FDA granted marketing approval to the **Praxis™ Extended RAS Panel** (Illumina, illumina.com), an NGS-test to detect certain genetic mutations in RAS genes in tumor samples of patients with metastatic colorectal cancer. The test is used to aid in the identification of patients who may be eligible for treatment with Vectibix (panitumumab). This is the first FDA-approved NGS test that can detect multiple RAS gene mutations for colorectal cancer in a single test. OI