tools

Approved Drugs

• The Food and Drug Administration (FDA) has approved a supplemental biologics license application (sBLA) for the use of **Arzerra**® (**ofatumumab**) (Genmab A/S, genmab.com) in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL).

• Amgen (amgen.com) announced that the FDA has approved the sBLA for **Blincyto**® (**blinatumomab**) to include new data supporting the treatment of pediatric patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

• Merck Sharp & Dohme Corp.'s (merck.com) **Keytruda**® (**pembrolizumab**) has received FDA approval in first-line non-small cell lung cancer (NSCLC). The FDA also broadened Keytruda's label, approving the drug for use in patients whose tumors express any level of PD-L1 in the second-line setting. Keytruda has also been granted accelerated approval by the FDA for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum-containing chemotherapy.

• The FDA has approved Genentech's (gene.com) **Tecentriq**® (**atezolizumab**) for people with a specific type of metastatic NSCLC.

• Astellas Pharma US, Inc. (us.astellas.com) and Pfizer Inc. (Pfizer.com) announced the FDA has approved a supplemental new drug application (sNDA) for **Xtandi**® (**enzalutamide**) **capsules** in advanced prostate cancer.

Drugs in the News

• Genentech (gene.com) has received a second breakthrough therapy designation from the FDA for **Alecensa**® (**alectinib**) for the treatment of adult patients with advanced ALK-positive NSCLC who have not received prior treatment with an ALK inhibitor.

• AbbVie (abbvie.com) submitted an sNDA to the FDA for **Imbruvica**® (**ibrutinib**) to treat patients with marginal zone lymphoma, a form of non-Hodgkin's lymphoma.

• Fate Therapeutics, Inc. (fatetherapeutics.com) announced that the FDA has granted orphan drug designation for **ProTmune**™ for "prevention of graft-versus-host disease in patients undergoing allogeneic hematopoietic cell transplantation."

Approved Devices

• Medeon Biodesign, Inc. (medeonbio.com/en) has received FDA 510(k) clearance for **AbClose**™, a single use, disposable laparoscopic port site closure device.

• GI View Ltd. (giview.com) has received FDA 510(k) clearance for the new **Aer-O-Scope**® **Colonoscope System**, a disposable, self-propelled, joystick-controlled, easy-to-use colonoscope system.

• Varian Medical Systems (varian.com) has received 510(k) clearance from the FDA to market the **Nexus DR**, a high resolution imaging system for X-ray imaging using a digital X-ray detector.

Approved Genetic Tests & Assays

• AstraZeneca (astrazeneca-us.com) announced that the FDA has approved a blood-based companion diagnostic for **Tagrisso**® (**osimertinib**). OI

FDA Approves Two-Dose Vaccination Regime

The FDA has approved a 2-dose vaccination regimen for **Gardasil**® **9** (**Human Papillomavirus 9-valent Vaccine, Recombinant**), for use in girls and boys 9 through 14 years of age.

FDA Modifies the Indication for Tarceva

FDA modified the indication for **Tarceva**® (**erlotinib**) (Astellas Pharma US, Inc., us.astellas.com) for the treatment of NSCLC to limit use to patients whose tumors have specific epidermal growth factor receptor (EGFR) mutations.