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Approved Drugs

- The Food and Drug Administration (FDA) has approved Exelixis, Inc.'s (exelixis.com) **Cabometyx™ (cabozantinib)** for the treatment of advanced renal cell carcinoma in patients who have received prior anti-angiogenic therapy.

- Eisai Inc. (eisai.com) announced that the FDA has approved **Lenvima® (lenvatinib) in combination with everolimus** for the treatment of patients with advanced renal cell carcinoma who were previously treated with an anti-angiogenic therapy.

- The FDA granted accelerated approval to Bristol-Myers Squibb's (bms.com) **Opdivo® (nivolumab)** for the treatment of patients with classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation and post-transplantation Adcetris® (brentuximab vedotin).

- Genentech Inc., (gene.com) announced that the FDA has granted accelerated approval to **Tecentriq (atezolizumab injection)** for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neo-adjuvant or adjuvant treatment with platinum containing chemotherapy.

Drugs in the News

- Amgen (amgen.com) announced that the FDA has accepted for priority review the supplemental biologics license application (sBLA) for **Blincyto® (blinatumomab)** to include new data supporting the treatment of pediatric and adolescent patients with Philadelphia chromosome negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia.

- The FDA has granted priority review for Eli Lilly and Company's (lillyoncology.com) biologics license application (BLA) for **olaratumab**, a PDGFRα antagonist, in combination with doxorubicin, for the potential treatment of people with advanced soft tissue sarcoma not amenable to curative treatment with radiotherapy or surgery.

- Bristol-Myers Squibb Company (bms.com) announced that the FDA has granted breakthrough therapy designation to **Opdivo (nivolumab)** for the potential indication of recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based therapy.

Approved Devices

- Hologic, Inc. (hologic.com) announced FDA clearance and commercial launch of the **Affirm™ prone biopsy system**, the first dedicated prone biopsy system to offer both 2D and 3D imaging-guided breast biopsies.

- The FDA has approved **Axumin** (Blue Earth Diagnostics, blueearthdiagnostics.com), a radioactive diagnostic agent for injection. Axumin is indicated for PET imaging in men with suspected prostate cancer recurrence based on PSA levels following prior treatment.

- Royal Philips (Philips.com) announced that the **Philips' suite of computed tomography (CT) solutions** has achieved 510(k) clearance from the FDA for low-dose lung cancer screening.

Genetic Tests & Assays in the News

- Roche (roche.com) announced the FDA approval of the first cytomegalovirus (CMV) test for use in hematopoietic stem cell transplant recipients. With this approval, the **Cobas® AmpliPrep/Cobas® TaqMan® CMV Test** is available for monitoring CMV treatment in all types of transplant patients in the U.S.

- The FDA has approved the **cobas EGFR Mutation Test v2** (Roche, roche.com), a blood-based companion diagnostic for the cancer drug Tarceva® (erlotinib). This is the first FDA-approved, blood-based genetic test that can detect epidermal growth factor receptor (EGFR) gene mutations in NSLC patients.

- The FDA has approved Roche's (roche.com) **Ventana PD-L1 (SP142) Assay** as a complementary diagnostic to provide PD-L1 status on patients who are considering treatment with the FDA-approved Roche immunotherapy Tecentriq™ (atezolizumab) for metastatic urothelial cancer.