FDA approvals for Roche oncology drugs

March 2019—Roche announced FDA approval of Tecentriq (atezolizumab) in combination with Avastin (bevacizumab) and paclitaxel and carboplatin for the initial treatment of people with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations. The approval is based on results from the phase three IMpower150 study, which showed that Tecentriq in combination with Avastin and chemotherapy helped people live longer, compared with Avastin and chemotherapy (median overall survival = 19.2 versus 14.7 months; hazard ratio = 0.78; 95 percent CI: 0.64–0.96; p = 0.016) in the intention-to-treat wild-type population.

In a separate release, the company announced that the FDA has granted accelerated approval to Venclexta (venetoclax) in combination with a hypomethylating agent (azacitidine or decitabine) or low-dose cytarabine for the treatment of people with newly diagnosed acute myeloid leukemia who are age 75 years or older, or for those ineligible for intensive induction chemotherapy due to coexisting medical conditions.

Roche, 317-521-2000