

Tecentriq combo for TNBC prolongs PFS

January 2019—The FDA has accepted Roche's supplemental biologics license application and granted priority review to the company's Tecentriq in combination with Abraxane (nab-paclitaxel, Celgene) for the initial treatment of people with PD-L1-positive, metastatic triple-negative breast cancer. The sBLA is based on data from the phase three IMpassion130 study, which was presented at the European Society for Medical Oncology Congress and published in the *New England Journal of Medicine* (Schmid P, et al. 2018;379[22]:2108-2121). Results demonstrate Tecentriq plus nab-paclitaxel as an initial treatment for unresectable locally advanced or metastatic TNBC significantly reduced the risk of disease worsening or death compared with nab-paclitaxel alone in all randomized patients and the PD-L1-positive population, a subgroup determined by PD-L1 biomarker testing. At this interim analysis, statistical significance was not met for overall survival in the ITT population, but the combination showed a clinically meaningful OS improvement in the PD-L1-positive population.

In a separate release, Roche announced results from the phase three ALESIA study, showing that Alecensa (alectinib) met its primary endpoint of investigator-assessed progression-free survival. Alecensa significantly reduced the risk of disease worsening or death by 78 percent, compared with crizotinib, when given as an initial monotherapy treatment in Asian patients with anaplastic lymphoma kinase-positive advanced or metastatic non-small cell lung cancer. Median PFS reported by the investigators was not yet reached in patients who received Alecensa versus 11.1 months in those who received crizotinib. The safety profile of Alecensa was consistent with that observed in previous studies.

[Roche](#), +41-61-688-1111