Tecentriq + Abraxane for TNBC gets accelerated approval

March 8, 2019–Genentech, a member of the Roche Group, today announced the FDA has granted accelerated approval to Tecentriq (atezolizumab) plus chemotherapy (Abraxane [paclitaxel protein-bound particles for injectable suspension (albumin-bound); nab-paclitaxel]) for the treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer whose tumors express PD-L1, as determined by an FDA-approved test.

“The Tecentriq regimen is an exciting new treatment option for certain people living with metastatic triple-negative breast cancer, a difficult-to-treat form of the disease,” Hayley Dinerman, executive director of the Triple Negative Breast Cancer Foundation, said in a release from Genentech. “Chemotherapy alone has been the mainstay of treatment for many years, so it’s encouraging to now have an immunotherapy combination available for people with PD-L1-positive disease.”

Approval is based on data from the phase three IMpassion130 study, which demonstrated that Tecentriq plus nab-paclitaxel significantly reduced the risk of disease worsening or death by 40 percent compared with nab-paclitaxel alone (median PFS=7.4 versus 4.8 months; HR=0.60, 95% CI: 0.48-0.77, $p<0.0001$) in PD-L1-positive patients with unresectable locally advanced or metastatic TNBC who had not received prior chemotherapy for metastatic disease. Overall survival results were immature with 43 percent of events in all randomized patients, and further data will be shared with the FDA and presented at an upcoming medical meeting, the company reports.