Ventana PD-L1 (SP142) assay approved as CDx for TNBC

March 22, 2019—Roche announced FDA approval of the Ventana PD-L1 (SP142) Assay as the first companion diagnostic to aid in identifying triple-negative breast cancer patients eligible for treatment with the company's cancer immunotherapy Tecentriq (atezolizumab) plus chemotherapy (Abraxane [paclitaxel protein-bound particles for injectable suspension (albumin-bound); nab-paclitaxel]). The assay was developed to enhance visual contrast of tumor-infiltrating immune cell staining.

"Triple-negative breast cancer is an aggressive disease that, until now, has had limited treatment options," Michael Heuer, CEO of Roche Diagnostics, said in a press release. "This assay plays a pivotal role in helping physicians identify patients that can benefit from Tecentriq therapy, providing better patient care."

Launched in 2016, the Ventana PD-L1 (SP142) Assay is the primary diagnostic assay within the Tecentriq clinical development program and was used to enroll and stratify patients in Tecentriq clinical trials. The assay was the first to evaluate patient PD-L1 biomarker status using immune cell staining and scoring within the tumor microenvironment.