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Hematogenix launches FDA approved companion diagnostic test for Triple-Negative Breast Cancer

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Hematogenix, a global leader in the field of integrated pathology services for drug development and immuno-oncology testing, today announced the launch of the companion diagnostic test for the drug TECENTRIQ. On March 8, 2019, the U.S. Food and Drug Administration (FDA) approved the immunotherapy TECENTRIQ in combination with Abraxane as frontline therapy for PD-L1-positive, unresectable locally advanced or metastatic triple-negative breast cancer (TNBC). TECENTRIQ is the first immunotherapy approved to treat breast cancer.

The companion diagnostic test that was approved by the FDA for selecting TNBC patients for TECENTRIQ is the VENTANA PD-L1 (SP142) assay. Hematogenix has extensive experience in performing PD-L1 testing for both the diagnostic and clinical trial markets. As a global leader in immuno-oncology testing, Hematogenix has validated all commercially available, and FDA approved PD-L1 assays, since early 2016.

"We have consistently provided broad commercial access to high-quality PD-L1 testing. It is our continued mission to help our physicians identify the most appropriate treatment options for their patients," said Hytham Al-Masri, M.D., CEO and Founder of Hematogenix. "This new advance in immunotherapy for patients with metastatic triple-negative breast cancer brings additional options for patients fighting this aggressive disease. I am proud of my team's involvement in the continuous research in this ground-breaking area of cancer."

The VENTANA PD-L1 (SP142) assay is an immunohistochemical assessment of the programmed death-ligand 1 (PD-L1) protein in tumor cells and tumor-infiltrating immune cells in formalin-fixed, paraffin-embedded (FFPE) tumor tissue.