Roche gains CE mark for expanded use of PD-L1 assay,11/17

November 2017—Roche announced the expanded use of the Ventana PD-L1 (SP142) Assay in non-small cell lung cancer and metastatic urothelial carcinoma in CE markets in which the Roche cancer immunotherapy medicine Tecentriq is approved. This assay evaluates patient PD-L1 status using immune cell and tumor cell staining within the tumor microenvironment, providing clinicians with information that may guide treatment decisions. It was previously approved by the FDA as a complementary diagnostic to provide PD-L1 status on patients with NSCLC and mUC who are considering treatment with Tecentriq.

Roche will continue to pursue worldwide regulatory approvals for the PD-L1 (SP142) assay in combination with Tecentriq for additional cancer indications. PD-L1 testing is not required for the use of Tecentriq, but it may provide additional information for physicians and patient dialogue. The PD-L1 (SP142) assay is for use with the Roche BenchMark series of automated staining instruments.

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