



Media Release

Roche receives FDA Approval for novel PD-L1 biomarker assay

The VENTANA PD-L1 (SP142) Assay approved as a complementary diagnostic for TECENTRIQ™ (atezolizumab) immunotherapy

Tucson, AZ, May 18, 2016 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced approval of the VENTANA PD-L1 (SP142) Assay¹ by the US Food and Drug Administration (FDA) as a complementary diagnostic to provide PD-L1 status on patients who are considering treatment with the FDA approved Roche immunotherapy TECENTRIQ™ (atezolizumab) for metastatic urothelial cancer (mUC). This test is the first to evaluate patient PD-L1 status using immune cell staining and scoring within the tumor microenvironment, providing clinicians with information that may guide immunotherapy decisions².

This personalized cancer immunotherapy and complementary diagnostic is the first major advancement in more than 30 years in the treatment of urothelial cancer (UC)³. UC is the fourth most common cancer in men in the United States and accounts for 5% of all new cancers reported. About 77,000 new cases of UC are diagnosed in the US annually, with approximately 16,000 deaths occurring each year. Men are three to four times more likely to suffer from this cancer⁴.

“We are very pleased with the FDA approval of our PD-L1 assay as a complementary diagnostic with TECENTRIQ™,” said Ann Costello, Head of Roche Tissue Diagnostics. “Through collaboration with our Roche Pharmaceuticals colleagues, we are committed to transforming science through innovative diagnostics and breakthrough medicines, providing patients a deeper understanding of their disease and immunotherapy options.”

“Roche’s ability to deliver a predictive test for our pathology customers, who provide important clinical information to oncologists, ultimately benefits patients in search of answers and treatment options,” said Jack Phillips, Head of Roche Diagnostics North America. “This assay, which supports patients with urothelial cancer – a disease with limited treatment options – has the potential to improve the standard of care.”

Roche will continue to pursue regulatory approval for the PD-L1 (SP142) assay in combination with TECENTRIQ™ in other cancer indications and in other countries. PD-L1 testing is not required for the use of TECENTRIQ™, but it may provide additional information for physicians and inform patient dialogue. The PD-L1 (SP142) assay is widely accessible for use with the company’s BenchMark ULTRA automated staining instrument.

¹This product is intended for in vitro diagnostic (IVD) use.

²The PD-L1 (SP142) assay is proven to select patients most likely to respond to treatment with TECENTRIQ™, as demonstrated by higher overall response rates in the IMvigor 210 clinical trial. The novel approach uses immunohistochemistry (IHC) technology designed to visually enhance and score PD-L1 protein on tumor-infiltrating immune cells. In an analysis based on 14.4 months of median follow up, TECENTRIQ™ shrank tumours (ORR) in 15 percent (95% CI: 11, 19) of people evaluable for efficacy (n=310) whose disease progressed after platinum-based chemotherapy. TECENTRIQ™ shrank tumors in 26 percent (95% CI: 18, 36) of people whose disease had medium and high levels of PD-L1 expression (n=100).



³UC cancer is also known as urothelial cell carcinoma, transitional cell carcinoma or the urinary tract or urothelial bladder cancer. The majority of urothelial tumors arise in the bladder with the remainder originating in the renal pelvis, urethra or ureter.

⁴American Cancer Society 2016 bladder cancer [statistics](#).

About the VENTANA PD-L1 (SP142) Assay

The PD-L1 (SP142) assay is available on the BenchMark ULTRA automated staining instrument and uses the OptiView DAB IHC Detection Kit with OptiView Amplification. The PD-L1 (SP142) assay performs specific staining of tumor cells and immune cells.

About atezolizumab

For more information on atezolizumab, visit the Genentech [website](#).

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalized healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognized as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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