

Roche's VENTANA PD-L1 (SP142) Assay approved as first companion diagnostic to identify triple-negative breast cancer patients eligible for treatment with Tecentriq in combination with Abraxane

- PD-L1 (SP142) was the enrollment assay used in the IMpassion130 trial, the first positive phase III immunotherapy regimen study in triple-negative breast cancer
- Each year about 300,000 women are diagnosed globally with triple-negative breast cancer, an aggressive disease with limited treatment options that represents 15 percent of all breast cancer cases¹
- This approval is an important step in Roche's personalized healthcare strategy to fit treatments to patients who can benefit most from a specific medicine

Basel, 11 March 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced US Food and Drug Administration approval of the VENTANA PD-L1 (SP142) Assay² as the first companion diagnostic to aid in identifying triple-negative breast cancer (TNBC) patients eligible for treatment with the Roche cancer immunotherapy Tecentriq® (atezolizumab)³ plus chemotherapy (Abraxane® [paclitaxel protein-bound particles for injectable suspension (albumin-bound); nab-paclitaxel]). Assessment of PD-L1 biomarker status on tumor-infiltrating immune cells with the assay is essential for identifying those patients most likely to benefit from the treatment.

A diagnosis of triple-negative breast cancer means that the three most common proteins associated with breast cancer growth – estrogen receptor, progesterone receptor and HER2/neu – are not expressed on the tumor.

“Triple-negative breast cancer is an aggressive disease that, until now, has had limited treatment options,” said Michael Heuer, CEO of Roche Diagnostics. “This assay plays a pivotal role in helping physicians identify patients that can benefit from Tecentriq therapy, providing better patient care. At Roche, we build on our capacity to research both targeted medicines and companion diagnostics under one roof, so we can provide the right treatment to the right patient at the right time.”

The VENTANA PD-L1 (SP142) Assay was developed to enhance visual contrast of tumor-infiltrating immune cell staining. In triple-negative breast cancer, PD-L1 is primarily expressed on tumor-infiltrating immune cells rather than on tumor cells themselves.

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.⁴

About the VENTANA PD-L1 (SP142) Assay

The VENTANA PD-L1 (SP142) Assay is available on the fully automated BenchMark ULTRA instrument⁵ and uses the OptiView DAB IHC Detection Kit with OptiView Amplification Kit. The VENTANA PD-L1 (SP142) Assay performs specific staining of tumor cells and immune cells. The assay was previously approved by the FDA and CE marked for use as a companion diagnostic in urothelial carcinoma (UC)³ and as a predictive assay in second-line non-small cell lung cancer (NSCLC) with Tecentriq. See the Tecentriq product label for more information on PD-L1 expression levels in therapeutic guidance for various cancer indications.

About the IMpassion130 study

The IMpassion130 study is a phase III, multicenter, randomized, double-blind study evaluating the efficacy, safety and pharmacokinetics of Tecentriq plus nab-paclitaxel compared with placebo plus nab-paclitaxel in people with unresectable locally advanced or metastatic triple-negative breast cancer who have not received prior systemic therapy for metastatic breast cancer (mBC). For details of the study go to www.roche.com.

About Tecentriq

Tecentriq is a monoclonal antibody designed to bind with a protein called PD-L1 expressed on tumour cells and tumour-infiltrating immune cells, blocking its interactions with both PD-1 and B7.1 receptors. By inhibiting PD-L1, Tecentriq may enable the activation of T cells. Tecentriq has the potential to be used as a foundational combination partner with cancer immunotherapies, targeted medicines and various chemotherapies across a broad range of cancers.

Tecentriq is already approved in the European Union, United States and more than 85 countries for people with previously treated metastatic NSCLC and for certain types of untreated or previously treated metastatic urothelial carcinoma (mUC). Tecentriq was also recently approved in the United States for the initial treatment of people with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumour aberrations and for the treatment of PD-L1 positive, metastatic triple-negative breast cancer.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

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. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty 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. Moreover, for the tenth consecutive year, Roche has been recognised as the most sustainable company in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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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References

- [1] Ferlay J, Soerjomataram I, Dikshit R, et al. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. *Int J Cancer* 2015;136:E359-E86.
- [2] This product is intended for in vitro diagnostic (IVD) use.
- [3] In Switzerland Tecentriq is approved for non-small cell lung cancer only.
- [4] The PD-L1 (SP142) Assay is proven to identify patients most likely to respond to treatment with Tecentriq, as demonstrated by higher overall response rates in Cohort 2 of 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 tumors (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).
- [5] In the US available on the BenchMark ULTRA instrument only.

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