Roche's VENTANA PD-L1 (SP263) Assay receives FDA approval as a companion diagnostic to identify certain non-small cell lung cancer patients eligible for Tecentriq® (atezolizumab)

- **Lung cancer remains the leading cause of cancer-related deaths worldwide, with more than 2.2 million people diagnosed globally last year.[1]**
- **The VENTANA PD-L1 (SP263) Assay helps determine which non-small cell lung cancer patients may benefit from treatment with Tecentriq immunotherapy based on the results of the Phase III IMpower010 study.**
- **This new test expands Roche's industry leading portfolio of companion diagnostics and builds on our commitment to improve personalized healthcare for better patient outcomes.**

Basel, 22 October 2021 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced U.S. Food and Drug Administration (FDA) approval of the VENTANA PD-L1 (SP263) Assay in non- small cell lung cancer (NSCLC) as a companion diagnostic test for Tecentriq, advancing the company's commitment to guide clinical decision making through innovative, high quality assays that improve patient access to personalized healthcare.

The current standard of care for patients with early stage lung cancer is surgery to remove the tumor, which may be followed by chemotherapy. Unfortunately, about half of these patients will have their cancer return following surgery.[2] Tecentriq received FDA approval on 15 October 2021 as adjuvant treatment following surgery and platinum-based chemotherapy for adults whose Stage II-IIIA NSCLC tumors have PD-L1 expression on ≥1% of tumor cells. The VENTANA PD-L1 (SP263) Assay identifies NSCLC patients who may be eligible for Tecentriq (atezolizumab) monotherapy in this indication.

"Early detection of lung cancer can change the treatment pathway for patients and give them more treatment options," said Thomas Schinecker, CEO Roche Diagnostics. "We are proud to offer a companion diagnostic PD-L1 test that identifies lung cancer patients who may qualify for Tecentriq therapy. With the FDA approval of this companion diagnostic test, clinicians now have an effective tool for offering better patient care through targeted immunotherapy treatment."

The VENTANA PD-L1 (SP263) Assay was used as part of the IMpower010 study sponsored by Genentech, a member of the Roche Group, to identify patients whose tumors expressed the PD-L1 protein. The IMpower010 clinical study began in 2015 with the goal of understanding how patients would respond to treatment with Tecentriq following traditional surgery and chemotherapy. In 2021, Genentech reported a 34% reduction in the risk of disease recurrence or death amongst Tecentriq patients whose tumors were shown to express PD-L1 protein. For details of the study go to www.roche.com.

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About the VENTANA PD-L1 (SP263) Assay
VENTANA PD-L1 (SP263) Assay is used to detect programmed death ligand-1 (PD-L1) protein in non-small cell lung carcinoma (NSCLC) patients. PD-L1 expression on tumor cells and immune cells has been shown in clinical studies to help predict the likelihood a patient may benefit from PD-L1/PD-1 immunotherapy drugs.[3-6]

VENTANA PD-L1 (SP263) Assay testing is performed on a BenchMark ULTRA instrument and is visualized using the OptiView DAB IHC Detection Kit.

Roche has developed a leading, comprehensive and differentiated lung cancer immunohistochemical portfolio, with biomarkers that support multiple guidelines for the diagnosis and stratification of lung cancers.[7-9]

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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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. More than 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 twelfth consecutive year, Roche has been recognised as one of the most sustainable companies 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 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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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