Media Release

Roche receives FDA approval of label expansion for VENTANA PD-L1 (SP263) Assay to identify patients with locally advanced and metastatic non-small cell lung cancer eligible for Libtayo

- **The VENTANA PD-L1 (SP263) Assay helps determine which patients with non-small cell lung cancer (NSCLC) may be eligible for treatment with Libtayo monotherapy[1] based on the results of the Phase III EMPOWER-Lung 1 study.**
- **This additional approval will allow more patients with locally advanced and metastatic NSCLC broader access to the immunotherapy Libtayo.**
- **PD-L1 testing provides clinicians with essential information that helps guide clinical decision making and improve patient outcomes.**

TUCSON, March 6, 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved the VENTANA PD-L1 (SP263) Assay as a companion diagnostic to identify non-small cell lung cancer (NSCLC) patients eligible for treatment with Libtayo® (cemiplimab), a PD-1 inhibitor therapy developed by Regeneron.

More than 60% of patients diagnosed with NSCLC are diagnosed at locally advanced or metastatic stage (Stage III-IV).[2] With this launch, more patients may have access to an additional immunotherapy option with Libtayo, potentially improving their treatment pathway and outcomes.

“Diagnostics, like our high-medical-value PD-L1 assay portfolio, enable personalized medicine to help improve patient outcomes,” said Jill German, head of Pathology Lab, Roche Diagnostics. “This approval helps physicians make more confident treatment decisions by identifying patients with tumors that may respond to the immunotherapy Libtayo.”

The VENTANA PD-L1 (SP263) Assay is the only FDA-approved product available with NSCLC indications for four different immunotherapy drugs, offering oncologists a broad range of treatment options for patients. Treating NSCLC as early as possible may improve patient outcomes.

Lung cancer is the leading cause of cancer death worldwide. Every year, more than 2.2 million people are diagnosed with lung cancer globally, and up to 85% of these cases are NSCLC.[3,4]

About the VENTANA PD-L1 (SP263) Assay

The 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.[5]

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.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalized healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognizing our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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.

References

[1] Regeneron news release. FDA approves LIBTAYO® (cemiplimab-rwlc) monotherapy for patients with first-line advanced non-small cell lung cancer with PD-L1 expression of ≥50% with no EGFR, ALK or ROS mutations as determined by an FDA-approved test. (Refer to product for full intended use.)

[2] EpiCast Report: NSCLC Epidemiology Forecast to 2025. GlobalData, 2016.

[3] World Health Organization: GLOBOCAN 2020 – Lung Cancer: Estimated cancer incidence, mortality and prevalence worldwide. [Internet; cited May 2021] Available from: https://gco.iarc.fr/today/data/factsheets/cancers/15-Lung-fact-sheet.pdf.

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[4] Cancer.org: What is non-small-cell lung cancer? [Internet; cited May 2021] Available from: https://www.cancer.org/cancer/lung-cancer/about/what-is.html#.

[5] VENTANA PD-L1 (SP263) Assay. U.S. Package Insert. Roche Diagnostics, 2023.

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