Roche receives FDA approval for VENTANA ALK (D5F3) CDx Assay to identify lung cancer patients eligible for targeted treatment with LORBRENA (lorlatinib)

- **About 235,000 people in the US will be diagnosed with lung cancer in 2021, with non-small cell lung cancer (NSCLC) accounting for 84 percent of all lung cancers[1]**
- **ALK – anaplastic lymphoma kinase – is an important biomarker found in NSCLC, and targeted therapies have been shown to dramatically improve progression-free survival compared to the previous standard of care[2,3,4]**
- **The VENTANA ALK (D5F3) CDx Assay[5] is now FDA approved as a companion diagnostic in four targeted treatments, providing more options to lung cancer patients**

Tucson, 9 March 2021 - Roche (SIX: RO, ROG; OTCQX:RHHBY) today announced US Food and Drug Administration (FDA) approval of the VENTANA ALK (D5F3) CDx Assay as a companion diagnostic to identify ALK-positive non-small cell lung cancer (NSCLC) patients eligible for treatment with Pfizer's drug LORBRENA® (lorlatinib). The VENTANA ALK (D5F3) CDx Assay is the only immunohistochemistry (IHC) test approved by the FDA as a companion diagnostic for LORBRENA.

ALK-positive patients treated with ALK inhibitors in previous studies have shown progression-free survival of up to nearly three years.[2] In contrast, progression-free survival for ALK-positive patients treated with chemotherapy in ALK inhibitor studies was seven to eight months.[3,4]

"This FDA approval is great news for ALK-positive patients," said Jill German, Head of Roche Pathology Customer Segment. "It is essential that we identify patients with this cancer biomarker quickly and accurately so they can be treated with effective targeted therapy. This label expansion advances Roche's commitment to personalised healthcare by providing lung cancer patients with access to more treatment options and a better chance for progression-free survival compared to the standard of care."

The VENTANA ALK (D5F3) CDx Assay is now FDA approved as a companion diagnostic in four targeted treatments - XALKORI® (crizotinib), ZYKADIA® (ceritinib), ALECENSA® (alectinib) and LORBRENA® (lorlatinib). The assay has been shown in studies to identify more NSCLC patients that may benefit from an anti-ALK target therapy than fluorescent in situ hybridisation (FISH) testing.[6,7,8,9] The VENTANA ALK (D5F3) CDx Assay is available in the US for use on the BenchMark ULTRA and BenchMark XT immunohistochemistry/in situ hybridisation (IHC/ISH) slide staining instruments.

About the VENTANA ALK (D5F3) CDx Assay
VENTANA ALK (D5F3) CDx Assay is intended for the qualitative detection of the anaplastic lymphoma kinase (ALK) protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung

cancer tissue stained with a BenchMark ULTRA or BenchMark XT automated staining instrument. It is indicated as an aid in identifying patients eligible for treatment with XALKORI® (crizotinib), ZYKADIA® (ceritinib), ALECENSA® (alectinib) or LORBRENA® (lorlatinib) in the US.

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information and proper controls. This product is intended for in vitro diagnostic (IVD) use. For more information, visit ALKIHC.com.

About LORBRENA
For more information on LORBRENA (lorlatinib), visit LORBRENA

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. 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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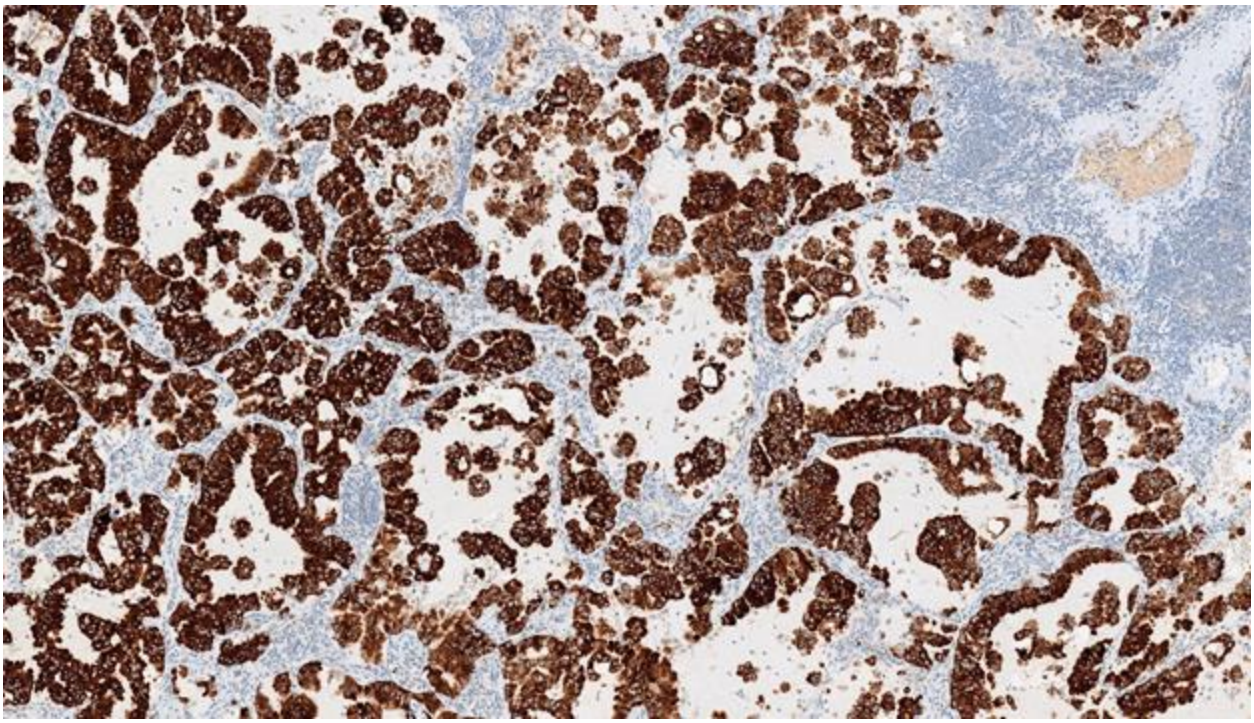

NSCLC tissue samples stained with the VENTANA ALK (D5F3) CDx Assay