Roche receives FDA approval for first companion diagnostic to identify dMMR solid tumour patients eligible for anti-PD-1 immunotherapy

- **Cancer is the second leading cause of death worldwide, with nearly 10 million deaths annually.[1, 2] In the U.S., approximately 1.9 million new cancer cases are expected to be diagnosed in 2021.[1]**
- **Based on cancer biomarkers, the first-of-its-kind VENTANA MMR RxDx Panel helps determine which solid tumour patients may benefit from GSK immunotherapy.**
- **Roche/GSK collaboration represents an important step towards a personalised healthcare strategy for certain solid tumour patients.**

Basel, 18 August 2021 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced U.S. Food and Drug Administration (FDA) approval of the VENTANA MMR RxDx Panel, advancing the company's commitment to personalised healthcare through tests that determine which patients are most likely to benefit from specific and targeted therapies. The VENTANA MMR RxDx Panel is the first companion diagnostic test to aid in identifying patients whose solid tumours are deficient in DNA mismatch repair (MMR), who may be eligible for JEMPERLI (dostarlimab-gxly) monotherapy, an anti-PD-1 immunotherapy from GSK. The test evaluates a panel of MMR proteins in tumours to provide important treatment information to clinicians.

MMR is a naturally occurring mechanism that scans our DNA, correcting errors that cause disease. When MMR is deficient (dMMR), cells mutate, which can lead to cancer. While MMR deficiency is most common in endometrial cancer, other high prevalence dMMR tumour types include gastric, colorectal, small intestine, cervical and neuroendocrine cancers. In the U.S., prevalence of dMMR across patients with solid tumours has been estimated at 14 percent.[3] PD-1 inhibitors can be effective treatment in cancers with MMR deficiency.

"As the first companion diagnostic of its kind, this test can help qualify patients with solid tumours that are deficient in MMR who have progressed in their disease and who have no other suitable treatment options," said Thomas Schinecker, CEO Roche Diagnostics. "Based on the results of our MMR biomarker test, these patients may be eligible to receive GSK's JEMPERLI. We are pleased that our innovative companion diagnostic label continues to grow to serve more patients."

FDA approval of the VENTANA MMR RxDx Panel provides clinicians with access to a fully automated panel of MMR biomarkers tested by immunohistochemistry (IHC), enabling impactful treatment decisions for patients. JEMPERLI was approved by the FDA on 17 August 2021 for the treatment of adult patients with dMMR recurrent or advanced solid tumours, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. This indication received accelerated approval based on tumour response rate and durability of response. Continued approval for this indication may depend on verification and description of clinical benefit in a confirmatory trial(s).

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The VENTANA MMR RxDx Panel and JEMPERLI were earlier approved by the FDA for use in endometrial cancer in April 2021.

Read more about Roche innovation in MMR biomarker testing.

About the VENTANA MMR RxDx Panel
The VENTANA MMR RxDx Panel is a label expansion of Roche's current on-market VENTANA MMR IHC Panel. The VENTANA MMR RxDx Panel is intended for the assessment of expression of MMR proteins in formalin-fixed, paraffin-embedded (FFPE) tumour tissue stained with OptiView DAB IHC Detection Kit and ancillary reagents in the panel for VENTANA anti-MLH1 (M1), VENTANA anti-MSH2 (G219-1129) and VENTANA anti-MSH6 (SP93) and OptiView DAB IHC Detection Kit with the OptiView Amplification Kit and ancillary reagents for VENTANA anti-PMS2 (A16-4) on a BenchMark ULTRA instrument. DNA mismatch repair (MMR) proteins have been clinically proven to be predictive biomarkers for PD-1 targeted therapy; specifically, a loss of expression of one or more MMR proteins might predict an increased likelihood of response to such therapy.[4,5,6] PD-1 inhibitors can be effective in cancers with MMR deficiency.[4,6] MMR is a conserved molecular mechanism that functions to correct the improper base substitutions that spontaneously occur during DNA replication. Defects in the MMR machinery have been attributed to mutations in the MMR proteins.

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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