Media Release

Roche receives FDA approval for the first companion diagnostic to assess PTEN protein in people living with prostate cancer

- **The new VENTANA PTEN (SP218) RxDx Assay fulfils an unmet medical need by helping clinicians identify patients with PTEN protein loss who may benefit from combination treatment with TRUQAP**
- **In prostate cancer, PTEN protein loss is associated with faster disease progression and reduced benefit from current standard-of-care treatments**[1]
- **The FDA approval reinforces Roche's leadership in companion diagnostics and its ongoing commitment to expanding personalised healthcare to improve patient outcomes**

Basel, 12 June 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the VENTANA® PTEN (SP218) RxDx Assay is the first immunohistochemistry (IHC) companion diagnostic test to receive U.S. Food and Drug Administration (FDA) approval for determining PTEN protein loss, also known as PTEN deficiency, in tumours of patients with prostate adenocarcinoma. These patients may now be eligible for treatment with AstraZeneca's targeted therapy TRUQAP® (capivasertib).

"Prostate cancer is one of the leading cancer diagnoses for men in the United States," said Matt Sause, CEO of Roche Diagnostics. "The FDA approval of our new companion diagnostic will provide clinicians with a vital tool to identify patients with PTEN loss and potentially provide new therapeutic options."

PTEN is a tumour suppressor protein and loss of PTEN is commonly observed in a variety of cancers.[2] Roche's test enables patients with PTEN-deficient prostate cancer to potentially benefit from a combination treatment with TRUQAP. TRUQAP provides a new, first-line treatment option for patients with PTEN-deficient metastatic androgen pathway modulation-naïve or sensitive (mAPMN/S) prostate cancer, previously referred to as metastatic hormone-sensitive prostate cancer (mHSPC).[3]

Metastatic hormone-sensitive prostate cancer is an aggressive form of prostate cancer and treatments specifically targeting the PTEN protein loss biology were previously not available. The average length of survival after new, metastatic prostate cancer diagnosis is about 5 to 6 years.[4] About 25% of patients with metastatic hormone-sensitive prostate cancer have PTEN-deficient tumors as evaluated by immunohistochemistry (IHC).[1]

Foundation Medicine, an independent affiliate of the Roche Group, is one laboratory using the VENTANA PTEN (SP218) RxDx Assay companion diagnostic kit to help healthcare providers identify patients with PTEN protein loss.

About the VENTANA PTEN (SP218) RxDx Assay

The VENTANA PTEN (SP218) RxDx Assay is a qualitative immunohistochemical assay intended to be used in the assessment of PTEN protein in prostate adenocarcinoma. The OptiView DAB IHC Detection Kit is used for staining on a BenchMark ULTRA instrument. The assay is indicated as an aid in identifying patients with prostate adenocarcinoma who may be eligible for treatment with TRUQAP in combination with abiraterone acetate in accordance with the approved therapeutic product labeling.

The approval of the VENTANA PTEN (SP218) RxDx Assay is based on the results of the CAPItello-281 clinical study where it was used as the enrollment assay to identify patients whose tumours exhibited PTEN deficiency. The clinical cutoff for PTEN protein loss status is ≥ 90% of viable malignant cells with no specific cytoplasmic staining. PTEN protein loss status is based on the pathologist's observation of an absence or presence of PTEN expression within prostate adenocarcinoma.[5] Patients who received combination therapy with TRUQAP experienced a statistically significant and clinically meaningful reduction in disease progression.[1]

About Roche

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

For more information, please visit www.roche.com.

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