Media & Investor Release

Roche launches PRAME (EPR20330) Antibody to identify PRAME protein expression in patients that may have melanoma

- **The PRAME (EPR20330) Antibody evaluates PRAME protein expression from patients with suspected melanoma.**
- **Understanding if the PRAME protein is expressed helps enable more informed clinical decisions and may improve patient outcomes.**
- **The PRAME (EPR20330) Antibody is the latest addition to Roche's robust dermatology portfolio with more than 50 dermatology biomarkers designed to meet a broad range of diagnostic needs.**

Basel, 11 October 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the launch of Anti-PRAME (EPR 20330) Rabbit Monoclonal Primary Antibody to identify PRAME protein expression in tissue samples from patients with suspected melanoma.

Because the PRAME (PReferentially expressed Antigen in MElanoma) protein is expressed in most melanomas, the PRAME (EPR20330) Antibody* is used as an aid to differentiate between benign and malignant lesions to help improve diagnostic decisions. If PRAME expression is detected, this suggests that the lesion is malignant.

"Every four minutes, one person dies from skin cancer. However, when detected early, localised melanoma is highly curable with a simple surgical excision," said Thomas Schinecker, CEO of Roche Diagnostics. "Identifying this critical biomarker helps clinicians determine if their patient has melanoma. We're proud to add the PRAME assay to our already comprehensive test menu of dermatology biomarkers that help inform a patient's diagnosis and treatment."

Melanoma is an aggressive skin cancer that originates from melanocytes, which are cells in the skin and eyes that produce and contain melanin. Melanoma develops when unrepaired DNA damage to melanocytes triggers mutations that cause the melanocytes to grow rapidly and form malignant tumours. When detected early, the 5-year survival rate is 99 percent.[1]

The first test that is used to evaluate a potential melanocytic lesion is a hematoxylin and eosin (H&E) stain of the patient's tissue sample. However, not all melanomas are easily diagnosed using H&E alone. Studies suggest that detection of PRAME expression by immunohistochemistry (IHC) complements findings from routinely used tests and enables more informed clinical decisions and improved patient outcomes.[2-4] In particularly challenging cases, use of PRAME IHC may highlight abnormal cells expressing the PRAME protein and provide more confidence in diagnosis of melanoma.

More information about PRAME will be presented at the International Academy of Pathology 2022 World Congress in Sydney, Australia on 14 October 2022 in a session titled “The diagnostic approach to melanocytic lesions”.

About the Anti-PRAME (EPR 20330) Rabbit Monoclonal Primary Antibody

The PRAME (EPR20330) Antibody is fully automated on the full line of Roche BenchMark IHC/ISH instruments. This antibody is validated for use using OptiView DAB IHC Detection, ultraView Universal DAB Detection & ultraView Universal Alkaline Phosphatase Red Detection Kits giving added flexibility to laboratories and pathologists' preferences.

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 personalised 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 recognising our endeavour 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.

*Anti-PRAME (EPR 20330) Rabbit Monoclonal Primary Antibody

References

[1] American Cancer Society.
[2] Lezcano, C. et al. PRAME expression in melanocytic tumors. Am J Surg Pathol 2018;42(11):1456-1465.
[3] Lezcano, C. et al. PRAME immunohistochemistry as an ancillary test for the assessment of melanocytic lesions. Surg Pathol Clin 2021 Jun;14(2):165-175
[4] Lezcano, C. et al. Immunohistochemistry for PRAME in the distinction of nodal nevi from metastatic melanoma. Am J Surg Pathol 2020;44(4):503-508.

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