Media Release

Roche launches two new antibodies to identify key clinical mutations in patients with brain cancer

- **Recent advances in cancer genomics have deepened the medical community's understanding of the molecular alterations in brain tumours, more precisely subclassifying patients into specific diagnoses.**
- **Understanding a patient's brain tumour mutation status in the IDH1 and ATRX genes enables more informed clinical decisions and may improve patient outcomes.**
- **The IDH1 R132H and ATRX antibodies are the latest additions to Roche's neuropathology portfolio, which contains 29 biomarkers.**

Basel, 23 February 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the launch of the IDH1 R132H (MRQ-67) Rabbit Monoclonal Primary Antibody and the ATRX Rabbit Polyclonal Antibody to identify mutation status in patients diagnosed with brain cancer.

A brain tumour is formed when there is an abnormal growth of cells in the brain. There are two main types of cells in the brain: neurons, the communicators of the nervous system and glial cells, which support and protect neurons and maintain the body's natural state of balance. Gliomas, brain tumours that develop from glial cells, are the most prevalent type of malignant brain tumours in adults.[1]

Gliomas that have mutations in the IDH1 and ATRX genes are biologically distinct from tumours that do not carry these mutations. Knowing a patient's IDH1 and ATRX mutation status enables clinicians to provide personalised care to patients based on their specific tumour classification, including a more informed prognosis, the selection of targeted therapies and inclusion in clinical trials.[2]

"A patient's IDH1 status helps determine eligibility for clinical trials, which offers more treatment options, and may one day lead to potential targeted therapies for people fighting brain cancer," said Matt Sause, CEO of Roche Diagnostics.

Time is critical for patients fighting brain cancer. Patients diagnosed with glioblastoma, the most common brain cancer in adults, have an average survival rate of less than one year. Having an understanding of a glioma patient's mutation status will enable clinicians to quickly determine the optimum treatment path for that patient and help predict therapeutic outcomes.

Immunohistochemistry is recommended by all major glioma practice guidelines for determining IDH1 R132H and ATRX mutation status.[3-5] When compared to sequencing,

identification of IDH1 R132H mutations via immunohistochemistry has been shown to be more accurate, rapid, accessible and cost effective.[6] The IDH1 assay can also detect the IDH1 R132H mutation in acute myeloid leukaemia (AML).

Roche's IDH1 and ATRX assays are optimised and fully-automated on the BenchMark series of instruments. The two tests are now available in the US. They will likely be available in other non-CE markets later this year and in countries that accept the CE mark in 2024.

About the IDH1 R132H (MRQ-67) Rabbit Monoclonal Antibody and the ATRX Rabbit Polyclonal Antibody

Roche's IDH1 R132H (MRQ-67) Rabbit Monoclonal Antibody can detect the IDH1 R132H mutation in adult-type gliomas and in acute myeloid leukaemia (AML). When present, IDH1 R132H is associated with a relatively favourable prognosis and is important in patient stratification for clinical trials.[2] IDH1 R132H immunohistochemistry is recommended by all major glioma clinical practice guidelines as the initial IDH testing modality.[3-5] Roche's ATRX Rabbit Polyclonal Antibody detects a mutation in the ATRX gene, providing significant diagnostic and prognostic information to clinicians. ATRX testing is considered "desirable" by the World Health Organization for IDH-mutant gliomas.[3]

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.

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