

## Roche launches first in vitro diagnostic IHC test to detect ROS1 protein in cancers

- Roche's VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody is the first and only in vitro diagnostic ROS1 immunohistochemistry assay on the market
- The biomarker may provide a cost-effective and efficient means to initially identify elevated ROS1 protein expression in cancer
- ROS1-positive cancer cases, which are predominantly found in younger non-smokers,<sup>1</sup> account for 1-2 percent of all non-small cell lung cancer (NSCLC) cases

Tucson, Ariz., May 28, 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the global launch of the VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody, the first and only in vitro diagnostic ROS1 immunohistochemistry (IHC) assay. The test detects the presence of ROS1 protein in tissue, and may be useful in identifying ROS1-positive cancer cases. Guidelines from the College of American Pathologists and the National Comprehensive Cancer Network recommend ROS1 testing for confirmed lung adenocarcinoma cases.<sup>2,3</sup>

As these types of cancer are rare, found in up to 2 percent of non-small cell lung cancer cases, the use of a ROS1 IHC biomarker may provide a cost-effective and efficient means of identifying cases with elevated ROS1 protein expression before confirming by another method, such as by fluorescence in situ hybridization (FISH) or next-generation sequencing.<sup>4</sup>

"Our highly sensitive ROS1 test is the first in vitro diagnostic IHC available for recommended lung cancer testing guidelines, with the added benefit of rapid turnaround time," said Jill German, Head of Roche Tissue Diagnostics. "While this is important in non-small cell lung cancer cases today, ROS1 is also being investigated in a number of clinical trials in other cancer types."

The VENTANA ROS1 (SP384) Rabbit Monoclonal Primary Antibody is a US class I/CE in vitro diagnostic device and is available for use on Roche's BenchMark series of automated staining instruments.

### About ROS1

Elevated ROS1 protein expression in tumour cells may indicate the presence of a ROS1 gene rearrangement.<sup>4</sup> As with NSCLC tumours that are positive for ALK (anaplastic lymphoma kinase), ROS1-positive lung tumours arise predominantly in younger, non-smoking individuals.<sup>1</sup> This is of particular significance, as some ALK inhibitors have been shown to also be active in tumours harbouring a ROS1 rearrangement.

Interest in identifying ROS1-positive cancer cases has increased in recent years, with clinical trials investigating the response of cancers harbouring a ROS1 rearrangement of tyrosine kinase inhibitors, targeted against ALK rearrangements.<sup>5</sup>

## **About Lung Cancer**

Lung cancer causes more than three deaths every minute, and is the most common cancer worldwide.<sup>6</sup> Each year, an estimated 2.1 million people are diagnosed.<sup>6</sup>

Lung cancer is divided into two main subtypes, non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). Up to 85 percent of all lung cancers are NSCLC, which can be further subtyped into adenocarcinoma, squamous cell carcinoma and large cell carcinoma.<sup>7</sup>

The need for accurate classification of these subtypes has been amplified with the introduction of targeted therapies.<sup>8</sup> Targeted therapies have shifted the lung cancer treatment paradigm away from being based only on histological subtype, to incorporating subtyping involving oncogenic mutations and fusions.<sup>8</sup>

Roche is committed to the development of innovative tools to better diagnose and subtype lung cancer.

## **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. 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 tenth consecutive year, Roche has been recognised as the most sustainable company 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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](http://www.roche.com).

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