

Roche improves speed and accuracy of non-small cell lung cancer diagnosis with launch of automated digital pathology algorithm

- **uPath PD-L1 (SP263) image analysis uses automated pre-computing and one-click scoring to enable quicker and accurate detection and measurement of tumour cell staining positivity**
- **Roche advances personalised healthcare with development of image analysis algorithms using artificial intelligence**
- **Faster, more accurate diagnoses are critical with non-small cell lung cancer, which accounts for about 85 percent of all lung cancer cases**

Basel, June 26, 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the CE-IVD launch of its automated digital pathology algorithm, the uPath PD-L1 (SP263) image analysis for non-small cell lung cancer (NSCLC). The algorithm provides pathologists with automated assessments of scanned slide images that are objective and reproducible and have the potential to aid diagnosis and, ultimately, targeted treatment options for patients.

Validated on the VENTANA PD-L1 (SP263) Assay, the algorithm is ready-to-use and integrated within the Roche uPath enterprise software, a universal digital platform for case management, collaboration and reporting. This algorithm will help pathologists to quickly determine whether tumours are positive for the PD-L1 biomarker, highlighting positively and negatively stained tumour cells with a clear visual overlay for easy reference. Patients with tumours that are positive for the PD-L1 biomarker may be eligible for targeted treatment.

“Improving diagnostic consistency and certainty is crucial in providing faster, higher-quality and more accurate diagnoses to cancer patients,” said Thomas Schinecker, CEO, Roche Diagnostics. “Our uPath PD-L1 (SP263) image analysis for non-small cell lung cancer is the first next-generation CE-IVD PD-L1 algorithm to the clinical market. It expands on our growing digital pathology suite for VENTANA assays that aid physicians in providing the most accurate treatment decisions for patients with the most common type of lung cancer.”

The algorithm’s whole-slide automated analysis uses artificial intelligence to provide, with one-click, an actionable assessment of the scanned slide images that is objective and reproducible. The uPath PD-L1 (SP263) image analysis (NSCLC) algorithm for digital pathology is for use on uPath enterprise software.

About uPath image analysis algorithm suite

The uPath image analysis algorithm suite for pathology decision support offers ready-to-use image analysis tools, providing fast, consistent and automated analysis so that pathologists can quickly, accurately and confidently assess immunohistochemistry/in situ hybridization and hematoxylin and eosin-stained slides. This launch of uPath PD-L1 (SP263) image analysis for non-small cell lung cancer follows the January 2019 release of the Roche uPath enterprise software. All algorithms in the suite for uPath software will provide image analysis of VENTANA DP 200 scanned slide images stained with a Roche tissue assay. Together,

Roche is delivering a new foundation of its digital pathology solution which will enable the development of artificial intelligence-based image analysis algorithms that can provide pathologists more tools to improve efficiency and precision.

Roche is delivering the end-to-end digital pathology solution from tissue staining to producing high-quality digital images that can be reliably assessed using automated clinical image analysis algorithms. Roche minimizes the variables that can impact analysis, and it is this end-to-end development that produces the quality results customers can depend on for making clinical decisions. With the acceleration of immunotherapy and the development of more complex assays, Roche is moving these traditionally research-oriented tools into routine clinical practice.

About the uPath PD-L1 (SP263) image analysis for NSCLC algorithm

The uPath PD-L1 (SP263) image analysis for NSCLC algorithm is intended for use as an aid to the pathologist in the detection and semi-quantitative measurement of PD-L1 protein in formalin-fixed, paraffin-embedded NSCLC tissue. When used with the CE-marked VENTANA PD-L1 (SP263) Assay, it is indicated for use as an aid in identifying patients for treatment with therapies with the $\geq 50\%$ PD-L1 TC positivity cutoff in accordance with the approved therapeutic product labeling. It is intended for in vitro diagnostic use as an aid to the pathologist in the display, detection, counting, review and classification of tissues and cells of clinical interest based on particular morphology, color, intensity, size, pattern and shape.

About non-small cell lung cancer

Lung cancer is the leading cause of cancer death globally.¹ Each year, 1.76 million people die as a result of the disease, translating into more than 4,800 deaths worldwide every day.¹ Lung cancer can be broadly divided into two major types: NSCLC and small cell lung cancer. NSCLC is the most prevalent type, accounting for about 85% of all cases.² NSCLC comprises non-squamous and squamous-cell lung cancer, the squamous form of which is characterised by flat cells covering the airway surface when viewed under a microscope.²

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. 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 eleventh 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 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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.

VENTANA and UPATH are trademarks of Roche. Other product names and trademarks are the property of their respective owners.

References

[1] World Health Organization. GLOBOCAN 2018; Lung Cancer: Estimated cancer incidence, mortality and prevalence worldwide. Available from: <http://gco.iarc.fr/today/data/factsheets/cancers/15-Lung-fact-sheet.pdf>. Accessed November 2019.

[2] American Cancer Society. What Is Non-Small Cell Lung Cancer? [Internet]: Available from: <https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html>. Accessed November 2019.

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