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Advancing diagnostics and treatment potentials to achieve global goal to eradicate hepatitis by 2030

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“To strengthen the continuum of care for infectious diseases by improving access to critical diagnostic tools, we have taken a multifaceted approach that invests in research and development, collaborates with global health organizations to address public health challenges” explains Lim Hong Yew, Lab & C-Suite Value Stream Lead at Roche Diagnostics Asia Pacific

Hepatitis is a major public health threat and leading cause of morbidity and mortality worldwide. Globally, 71 million people are living with Hepatitis C (HCV) chronic infection. Asia Pacific region (APAC), accounts for 63% of the global death toll from hepatitis, numbering one million each year, a death rate three times higher than that of HIV/AIDS. In 2016, the World Health Assembly unanimously adopted the resolution calling for the eradication of viral hepatitis by 2030. Since then, hepatitis testing and treatment have been made more accessible, yet many countries – particularly low- and middle-income countries (LMICs) – are still far from achieving the elimination goal. Global Pharmaceutical and Diagnostics leader such as Roche contribute solutions to address different throughputs and disease areas to meet the global effort to eliminate viral hepatitis diseases.

Lim Hong Yew, Lab & C-Suite Value Stream Lead at Roche Diagnostics Asia Pacific (Singapore) explains objectives and diagnostic potentials whilst entailing global efforts to combat hepatitis.

- **How do you describe Roche's commitment to advance improved diagnostics and treatment potentials for hepatitis A/B/C? How does Roche strategize opportunities and challenges in this direction?**

At Roche, our commitment to advancing diagnostics and treatments for hepatitis A, B, and C is unwavering. We focus on developing and refining diagnostic solutions to support effective treatment and management of these viral infections. Our strategy involves a multifaceted approach: investing in research and development to stay at the forefront of diagnostic innovation, collaborating with global health organisations to address public health challenges, and continuously adapting our solutions to meet the needs of diverse healthcare settings. By shining a light on hepatitis, Roche is committed to moving the cause a few steps closer to achieving the WHO 2030 hepatitis elimination goals.

- **How do you define Roche's integrated approach to developing solutions for HCV and HBV? What are the strategic alliances Roche is embarking to achieve the objective?**

At Roche, our commitment to eliminating hepatitis is driven by a patient-centric approach and a dedication to advancing our infectious disease diagnostics portfolio. We recognize that effective diagnostic solutions require long-term partnerships and integration across various disease areas and throughputs. Our integrated solutions are designed to address the evolving needs of countries working towards the elimination of viral hepatitis.

Roche's approach to hepatitis C (HCV) and hepatitis B (HBV) combines state-of-the-art diagnostics with comprehensive treatment solutions. We are focused on developing advanced diagnostic tools that support early detection and effective management of these infections. Our strategy includes forming strategic alliances with key stakeholders, such as healthcare providers, research institutions, and patient advocacy groups. These collaborations are crucial for enhancing our diagnostic capabilities, driving research and innovation, and supporting global efforts to combat hepatitis.

Additionally, Roche is an active member of the APAC Liver Disease Alliance, where we contribute to an ecosystem approach aimed at addressing the rising burden of liver diseases across the region.

- **How does Roche enhance access to critical and robust diagnostic tools to strengthen the continuum of care for infectious diseases? What is your strategy for navigating disparities?**

At Roche, we are committed to enhancing access to critical diagnostic tools to strengthen the continuum of care for infectious diseases. Our approach includes launching initiatives like the Global Access Program, which aims to provide reliable testing solutions to patients in low- and middle-income countries (LMICs). By partnering with international agencies, NGOs, and governments, we work to improve health system diagnostic capacities and address disparities. Our goal is to ensure that everyone, regardless of their location or economic status, has access to the diagnostic tools necessary for effective disease management.

- **In many LMIC countries, access to affordable generic viral hepatitis medicines remains a challenge. How does Roche strive to alleviate these problems?**

Regardless where you are located in the world, chances are viral hepatitis is an issue; ranging from societal attitudes to the "culture of silence" taboos, ranging from the disease burden on the healthcare systems to getting access to proper testing and diagnosis

Roche recognizes that access to affordable medicines is a significant challenge in many LMICs. To address this, we leverage our Global Access Program to provide reliable diagnostics and collaborate with stakeholders to improve the accessibility of essential medicines. By working with governments, NGOs, and other partners, we aim to reduce barriers to access and ensure that patients in LMICs can benefit from effective treatments for viral hepatitis.

- **Describe Roche's strategies in developing innovative immunoassays to detect hepatitis C?**

Hepatitis C (HCV) is often not identified in its early stages as the majority of newly infected patients will be asymptomatic, and can remain so until serious liver damage has occurred. There can be a lack of specific clinical symptoms in the early stage in those who do present with symptoms, yet only people who know they are infected can be treated. The earlier HCV infection is diagnosed, the earlier optimum treatment can be offered. For access to effective treatment, it is important to determine whether the causative agent of hepatitis is viral in origin. Direct viral markers, such as HCV core antigen (HCV cAg) and HCV RNA, appear earlier than anti-HCV antibodies which occur approximately 6 to 12 weeks after infection.

Roche's latest Elecsys® HCV Duo assay provides real diagnostic benefits for detecting HCV infection by significantly shortening the diagnostic window period by up to 3 weeks compared with traditional testing regimens, based on first-line anti-HCV antibody testing only. The fully automated Elecsys® HCV Duo assay combines dual detection of HCV core antigen and antibodies to HCV and is the only fully automated assay that utilizes two separate, but parallel tests, generating combined and separate results to detect a direct viral marker (HCV core antigen) and the body's response to HCV infection (antibodies to HCV). It is also a solution that can simplify the hepatitis diagnostic pathway.

The latest Elecsys® HCV Duo assay expands Roche's comprehensive viral hepatitis test portfolio, which includes molecular and serology solutions, to help diagnose and manage patients with acute or chronic viral hepatitis infection. Roche's commitment to advancing hepatitis C diagnostics underscores the belief that everyone deserves access to early and accurate testing, as anyone can contract hepatitis but no one deserves it.

- **In order to advance precision medicine and patient access to targeted treatments, how does Roche envision expanding its digital pathology capabilities for companion diagnostics?**

As market leaders in companion diagnostics, Roche brings innovations to personalised healthcare, especially by harnessing the potential of Digital Pathology.

The Roche Digital Pathology "Open Environment" allows software developers to easily integrate their image analysis tools for tumour tissue with Roche's navify® Digital Pathology, a software designed for the pathologist's clinical case workflow. The Open Environment enables software developers globally to distribute their digital products through Roche's navify Digital Pathology, offering a broader set of diagnostic tools for pathologists and ultimately, the potential for better and faster answers for patients.

Earlier this year, we announced our collaboration with a global leader in artificial intelligence (AI)-powered technology for pathology. PathAI will exclusively work with Roche Pathology Lab to develop artificial intelligence (AI) digital pathology algorithms for Roche Pathology Lab's companion diagnostics business. The image analysis algorithms will be deployed on Roche's navify Digital Pathology platform, allowing seamless integration into pathology laboratories worldwide.

Roche Digital Pathology Dx (VENTANA DP 200), has received 510(k) clearance from the United States Food and Drug Administration (FDA), for primary Diagnosis. Primary diagnosis for digital pathology streamlines the digital workflow that empowers pathologists to make a timely diagnosis from anywhere.