Media & Investor Release

Roche granted FDA Breakthrough Device Designation for blood test measuring Lp(a) – a key marker for hereditary cardiovascular risk

- **Approximately one in five people worldwide have elevated Lp(a) levels, putting them at increased risk of cardiovascular diseases including myocardial infarction and stroke.[1]**
- **The Roche Diagnostics Tina-quant® Lp(a) assay measures lipoprotein (a) in a person's bloodstream, and will be made available on Roche's installed base of over 90,000 serum work area (SWA) systems worldwide.**
- **The test has been developed in collaboration with Amgen.**

BASEL, May 22, 2024 – Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the Tina-quant® lipoprotein Lp(a) RxDx assay has received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) to identify patients who may benefit from innovative Lp(a)-lowering therapy currently in development. Lipoprotein (a), or Lp(a), is emerging as an important, yet under-recognized, potential risk factor for cardiovascular disease, a major public health issue.

"While modern lifestyles are a major driver, as much as 30% of mortality associated with cardiovascular disease occurs in individuals without modifiable risk factors,"[2] said Matt Sause, CEO of Roche Diagnostics. "Lp(a) is a critical marker for people at risk of cardiovascular disease, but medicine has had limited solutions to adequately address the problem.Through our collaboration with Amgen, Roche is paving the way to make elevated Lp(a) an actionable biomarker."

"Lp(a) testing rates are markedly low, and existing lab tests may not consistently and accurately measure Lp(a) levels,"[3] said Jay Bradner, M.D., executive vice president of Research and Development and chief scientific officer at Amgen. "By combining Amgen's deep legacy and expertise in cardiovascular disease with Roche's diagnostic expertise, we can accelerate access to more standardized testing and equip more patients and healthcare providers with important information to better understand their risk for cardiovascular disease."

Once approved, the new Tina-quant® test is expected to be made available to support the selection of patients who may benefit from an innovative Lp(a)-lowering therapy.

About Lp(a)

Globally, as many as one in five people have elevated Lp(a),[1] in which lifestyle interventions such as diet and exercise have no significant impact. While Lp(a) levels can be influenced by non-genetic factors including menopause, kidney and liver diseases, and hyperthyroidism, they

are predominantly (>90%) determined by genetic variations in the lipoprotein (a) (LPA) gene.[4] Raised Lp(a) is particularly prevalent among women and people of African descent.[5,6]

High levels of Lp(a) have been shown to promote the buildup of lipids in artery walls, leading to the development of plaques, and have been associated with an increased risk of cardiovascular (CV) events.[4] Lp(a) testing is therefore an important tool for clinicians, enabling them to make a more accurate assessment of CV risk, and it is expected to become a part of regular diagnostic testing in the coming years.

Professional bodies around the world, including the National Lipid Association, Canadian Cardiovascular Society, European Atherosclerosis Society, European Society of Cardiology, and the Beijing Heart Society have recommended that Lp(a) measurement should be considered at least once in every adult person's life.

As Lp(a) has no single, defined molecular weight, there is a consensus in the scientific community that, ideally, Lp(a) levels should be measured in terms of the number of molecules per liter of blood (nmol/L). This contrasts with widely available tests that measure the molecular weight of Lp(a) in the blood (mg/L).

About Tina-quant® Lp(a) RxDx assay

The FDA has granted Breakthrough Device Designation to the Tina quant Lp(a) RxDx assay for use in selecting patients with elevated Lp(a) and a history of atherosclerotic disease for treatment with an Lp(a)-lowering drug. A lipoprotein (a) test involves a routine blood draw, during which a small sample of blood is used for measurement. This test measures the number of Lp(a) molecules per liter in a person's bloodstream, which paves the way for Lp(a) to serve as an actionable biomarker in future. If approved, it will be available on selected **cobas**® platforms.

Currently, there is no FDA-authorized Lp(a) assay measuring Lp(a) in nmol/L available in the U.S. This assay will be part of Roche's wider portfolio of tests for cardiovascular diseases. Together, these tests provide healthcare professionals the opportunity to make informed decisions, allowing patients to access new and innovative treatments.

About Breakthrough Device Designation

The Breakthrough Devices Program is a voluntary program for certain medical devices that provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition. This program is designed to expedite the development and review of these medical devices.

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 personalized 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 recognizing our endeavor 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 fifteenth 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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Roche Diagnostics U.S. Media Relations
us.mediarelations@roche.com

Jennifer Hoopingarner
Phone: 1-317-797-9741
Email: jennifer.hoopingarner@roche.com