Media Release

Roche receives FDA approval of cobas® pro serology solution for serological screening to protect the safety of the U.S. blood and plasma supply

- **With the addition of a new serology solution, Roche is the only comprehensive testing provider for the U.S. blood and plasma industry.**

INDIANAPOLIS – July 10, 2023 – The U.S. Food and Drug Administration (FDA) has approved the cobas® pro serology solution for infectious disease serological screening of blood and plasma donations. The cobas pro serology solution joins Roche's cobas® 6800/8800 molecular systems to form the first comprehensive testing solution for protecting the safety of the U.S. blood and plasma supply.

"The FDA approval of the cobas pro serology solution continues Roche's commitment to innovation to provide access to a wide range of disease-state tests to enable the safe supply of lifesaving blood and plasma products for patients," said Brad Moore, president and CEO, Roche Diagnostics North America.

This approval includes the cobas pro serology solution and the first of a menu of tests, the Elecsys® HIV Duo for the qualitative detection and differentiation of HIV-1 p24 antigen and antibodies to HIV, HIV-1 (groups M and O) and HIV-2. With the addition of cobas pro serology solution, Roche is providing a complete solution to help screening centers achieve greater workflow efficiency and timely results.

Blood and plasma centers need solutions that can safely and efficiently screen blood products while ensuring needed blood and plasma get to patients quickly. The addition of the cobas pro serology solution addresses these challenges by delivering:

- A modular and scalable design that allows for enhanced redundancy to meet the critical turnaround time objectives of blood and plasma centers.
- A higher level of laboratory efficiency and test menu consolidation through its integration with Roche's market leading molecular, automation and IT products.
- A consistent approach to compliance features across the serology and molecular platforms to drive ease of use.

Ensuring access to safe and reliable blood supply is critical for the effectiveness of the healthcare system. Blood transfusions and plasma-derived therapeutics help to save lives every day.

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 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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