Media Release

Roche receives FDA De Novo authorization for cobas® pro i 601 platform with Ionify® Gabapentin assay, advancing automated mass spectrometry for routine clinical laboratories

- **FDA De Novo authorization for the cobas® pro i 601 platform with Ionify® Gabapentin assay expands Roche's mass spectrometry menu into therapeutic drug monitoring.**
- **Designed to simplify traditionally complex testing, the solution brings the analytical capabilities of mass spectrometry together with an automated, standardized laboratory workflow.**
- **Roche will utilize an FDA-authorized Predetermined Change Control Plan (PCCP) to accelerate future clinical mass spectrometry menu expansion while maintaining rigorous safety and quality standards.**

INDIANAPOLIS, November 16, 2026 – Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has granted De Novo authorization for the **cobas® pro** i 601 platform with the Ionify® Gabapentin assay, components of its **cobas®** Mass Spec solution. Designed to bring advanced mass spectrometry testing into routine clinical laboratories, the solution combines the analytical capabilities of mass spectrometry with an automated, standardized workflow – expanding Roche's diagnostic menu into therapeutic drug monitoring.

Mass spectrometry is widely used for clinical applications requiring highly sensitive and specific measurement, but traditional methods often involve specialized personnel and complex manual workflows. Roche is pioneering the transition of mass spectrometry from specialized reference facilities to the core laboratory, redefining complex testing into an accessible, standardized solution for routine clinical practice.

Authorized through the De Novo pathway, the Ionify® Gabapentin assay adds a therapeutic drug monitoring application to a U.S. menu that includes 25-Hydroxy Vitamin D total and steroid hormone testing assays, such as estradiol and 17-Hydroxyprogesterone. Roche continues to develop additional clinical mass spectrometry assays to broaden the menu over time. Demonstrating an innovative, collaborative approach with the FDA, Roche will leverage a Predetermined Change Control Plan (PCCP), to drive and accelerate future clinical mass spectrometry menu expansion while still maintaining rigorous safety and quality standards. The authorized PCCP includes the expansion of up to 22 Ionify® assays on the **cobas® pro** i 601 platform as PCCP requirements are met. These additional assays are not yet available and will be introduced in the future as applicable requirements are met.

“Some of the best diagnostic technologies are often very complex and, in the end, don't actually reach patients," said Dan Malarek, President and CEO of Roche Diagnostics North America. “Mass spectrometry has long been valued for its analytical performance, but the complexity of traditional workflows has limited its use in routine laboratories. By automating and standardizing this technology, we’re helping make sophisticated testing more accessible to laboratories, clinicians and patients who depend on reliable results.”

About the cobas® Mass Spec solution

Mass spectrometry is widely regarded as a gold-standard analytical method for certain clinical applications, including steroid hormone measurement, vitamin D testing and therapeutic drug monitoring. The **cobas®** Mass Spec solution combines the high specificity, sensitivity and accuracy of mass spectrometry with an automated, standardized workflow designed to make this traditionally complex technology more accessible to routine clinical laboratories.

In July 2025, the **cobas®** Mass Spec solution received the Best New Clinical Diagnostics Instrumentation of 2024 award in the Scientists' Choice Awards® 2025, recognizing innovation in clinical laboratory technology.

For more information about **cobas®** Mass Spec solution, please visit go.roche.com/ClinicalMassSpec.

About Roche

Roche is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland, in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

For more information, please visit www.roche.com.

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