Indianapolis, March 23, 2016

Roche submits filing to FDA for cobas®® Procalcitonin (PCT) assay to help clinicians assess response of septic patients to treatment

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced that it has submitted the Elecsys BRAHMS PCT (Procalcitonin) assay for Premarket Notification (510k) to the U.S. Food and Drug Administration (FDA) as a dedicated testing solution for people with severe sepsis or septic shock.

The Elecsys BRAHMS PCT assay is a sensitive and specific biomarker for bacterial infection. A change in Procalcitonin levels over time, in conjunction with other laboratory findings and clinical assessments will aid in assessing the cumulative 28-day risk of mortality for patients with severe sepsis or septic shock who are admitted to the intensive care unit.

“Given the precarious nature of managing septic patients, it’s important for physicians to have the information they need to quickly identify at-risk patients,” said Dr. Alan Wright, Chief Medical Officer, Roche Diagnostics Corporation. “Getting the right treatment, to the right patient, at the right time is always important. With septic patients, this process is especially critical. Once approved, the Elecsys BRAHMS PCT assay will provide fast, (18-minute) reliable results that will enable clinicians to confidently provide the appropriate care to manage sepsis.”

About Sepsis

Sepsis contributes to more than 1.6 million hospitalizations annually in the U.S., and has a high mortality rate. Sepsis is a potentially life-threatening complication that can arise when the body develops a severe, over pronounced inflammatory response to an infection. If unchecked, sepsis can rapidly progress leading to organ dysfunction and if not managed properly, may lead to death of the patient. Clinical manifestations of sepsis can be vague and may progress undetected by signs and symptoms to a severe condition.

While any individual with a severe infection has the potential to develop sepsis, the very young, the elderly and the immunocompromised are particularly vulnerable. Early diagnosis and management of sepsis, usually with antibiotics and large amounts of intravenous fluids, improves chances for survival.
About the performance of the Elecsys BRAHMS PCT assay

The Elecsys BRAHMS PCT assay is designed to provide full automation, which means no reagent preparation or hands-on testing is required. This fast, reliable assay offers same-day testing capability with a short incubation time of only 18 minutes. It also has a broad measuring range (0.02 – 100 ng/mL, extending to 400 ng/mL with a recommended 1:4 dilution).

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. 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. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalized healthcare—a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine 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. Roche has been recognized as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 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.

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