

Indianapolis, July 13, 2018

## **Roche PCT assay cleared for expanded use – Important tool in antibiotic resistance crisis**

**Elecsys® B·R·A·H·M·S PCT™ (procalcitonin) helps clinicians assess presence and severity of certain bacterial infections and patient response to antibiotics**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received clearance from the U.S. Food and Drug Administration (FDA) for the expanded use of its Elecsys® B·R·A·H·M·S PCT™ assay to aid in antibiotic therapy decision making.

“There is a global health crisis caused by the emergence and proliferation of resistant bacteria,” said Dr. Alan Wright, Chief Medical Officer, Roche Diagnostics Corporation. “With this assay’s expanded claims, clinicians now have an important tool in the battle against antibiotic resistance and are better equipped to provide patients the right treatment, for the right period of time.”

The Elecsys B·R·A·H·M·S PCT was previously cleared by the FDA to evaluate the risk of progression to severe sepsis and septic shock in critically ill patients and 28-day mortality after diagnosis. The assay may now be used to support antibiotic treatment decisions in patients with suspected or confirmed sepsis and suspected or confirmed lower respiratory tract infections (LRTIs), defined as acute exacerbations of chronic obstructive pulmonary disease (aeCOPD), community acquired pneumonia (CAP), and acute bronchitis.

“This is an important step in the global struggle against antibiotic resistance. The quality and legacy of Roche Diagnostics’ Elecsys B·R·A·H·M·S PCT will enable doctors to feel more confident in their decisions when managing these patients,” said Mathias Egermark, MD, Vice President and International Business Leader, Cardiac and Critical Care, Roche Diagnostics International.

### **About the Elecsys B·R·A·H·M·S PCT assay**

This 18-minute assay is designed to measure procalcitonin (PCT) levels in the blood. Elevated PCT levels in a patient indicate a likely bacterial infection, while low PCT levels in a patient who has symptoms of infection may indicate the cause to be viral or non-infectious in nature. The kinetics of PCT also provide important insights into a patient’s response to antibiotics, which helps clinicians determine when to change or stop treatment. Elecsys B·R·A·H·M·S PCT assay may be added to any of the **cobas**® immunoassay instruments, offering access to critical insights in low-, mid- and high-volume laboratories.

### **About Roche**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives. 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.

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. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims for improving patient access to medical innovations by working with all relevant stakeholders. 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 nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed more than 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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](http://www.roche.com).

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Medical Approval	Laura Parnas Medical 13-Jul-2018 14:40:51 GMT+0000
Regulatory Approval	David Piechocki Regulatory 13-Jul-2018 16:22:50 GMT+0000

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