Media Release

Indianapolis, January 19, 2017

Breakthrough development for Americans with suspected heart attack – Next generation Troponin T test from Roche cleared by FDA

New Troponin T 9-minute test offers greater sensitivity in the diagnosis of myocardial infarction

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced that it has received the 510(k) clearance for its Elecsys Troponin T Gen 5 STAT (TnT Gen 5 STAT) blood test for patients with a suspected heart attack. With this clearance, Roche is the first IVD company in the U.S. to provide the next generation Troponin testing for patients as an aid in the diagnosis of myocardial infarction, enabling clinicians to more accurately identify patients experiencing a heart attack.

Every minute counts
Every 43 seconds someone in the U.S. has a heart attack, or acute myocardial infarction (AMI), which occurs when the blood supply to an area of the heart is interrupted. The longer time the heart is without proper blood supply, the greater the damage. Troponin, a specific marker of cardiac cell death, is released into the blood stream when cardiac cells are being damaged.

Patients with chest pain and other symptoms suggestive of AMI account for approximately 8 million of all emergency room consultations in the U.S., but only a fraction of them (5-20%) are actually having an AMI. Hence, fast and accurate diagnosis of AMI requires sensitive diagnostic tests that can detect early troponin release, allowing healthcare providers to make confident clinical decisions for their patients and appropriately manage hospital resources. In a heart attack, early diagnosis and initiation of treatment can reduce the amount of cardiac cell death thus potentially saving and improving quality of lives. This next generation Troponin T test from Roche is able to provide accuracy at lower levels of troponin to aid in correctly identifying patients having an AMI.

Moreover, this next generation of TnT test from Roche has been available in the rest of the world for the past seven years during which time it has been rapidly adopted by clinicians and its clinical diagnostic utility is supported by more than 600 peer-reviewed publications.

“As an emergency doctor whose job is to make decisions on patients with chest pain, my ability to do this safely and accurately is driven by the sensitivity of the troponin assay. FDA clearance of this new Roche TnT assay is easily the best news in the last decade for emergency medicine patients presenting with chest pain.”

Frank Peacock MD, FACEP – ED Physician

Baylor Medical Center Houston – Houston, TX
The Elecsys TnT Gen 5 test from Roche enables better decisions

The Elecsys® Troponin T Gen 5 STAT test from Roche detects cardiac troponin which is the preferred biomarker for the diagnosis of heart attack in clinical practice. In combination with an electrocardiogram (ECG) and signs of ischemia, troponin has become the gold standard as an aid in the diagnosis of heart attack. The higher sensitivity of the Roche TnT Gen 5 STAT assay in conjunction with the rapid turnaround time of nine minutes can significantly accelerate decision-making, and allows the detection of smaller infarctions thereby maximizing the potential for effective treatment.

With such compelling clinical utilities and the automation advantages associated with Roche solutions, the Elecsys TnT Gen 5 STAT test can provide the confidence that healthcare professionals need to diagnose and manage patients in emergency settings and beyond.

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, anti-malarials and cancer medicines. Roche has been recognized as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry eight 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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