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FDA clears Roche's LightCycler® MRSA Advanced Test for use in the U.S.

Easy-to-use molecular test offers faster results to help healthcare facilities control spread of methicillin-resistant Staphylococcus aureus (MRSA)

PLEASANTON, Calif. – Roche Molecular Systems, Inc. (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food & Drug Administration (FDA) cleared its new LightCycler® MRSA Advanced Test for the detection of methicillin-resistant *Staphylococcus aureus* (MRSA) for clinical use in the United States. The LightCycler® MRSA Advanced Test is a qualitative in-vitro diagnostic test for the direct detection of nasal colonization with bacterial MRSA, and it is designed to aid in the prevention and control of MRSA infections in healthcare settings. Roche's new real-time polymerase chain reaction (PCR) test delivers rapid results (within two hours) and appears to have better sensitivity compared to direct culture-based methods.

"It is important that healthcare professionals have access to MRSA testing technology that provides rapid and reliable results, allowing faster implementation of appropriate infection control measures," said Paul Brown, Ph.D., president and CEO, Roche Molecular Diagnostics. "Roche's new LightCycler® MRSA Advanced Test is designed to offer a simple, flexible, and reliable method for MRSA screening to support hospitals in the prevention of MRSA infections."

High rates of infection, mortality, and high costs of treatment due to healthcare-associated infections (HAIs) caused by MRSA are a critical issue for healthcare facilities worldwide. In addition, community-associated MRSA (CA-MRSA) infection has spread in the U.S., feeding the pipeline of infection in hospitals, and underscoring the need for comprehensive infection control programs along with more rapid and reliable MRSA screening methods. In response to this public health issue, an increasing number of states have passed legislation requiring mandatory reporting and/or screening for HAI's.

"The introduction of this new advanced test will expand the options healthcare facilities have for MRSA screening using molecular diagnostic methods," said Lance Peterson, M.D., FASCP,

epidemiologist and a founder of the MRSA screening program at NorthShore University HealthSystem in Evanston, Illinois. "The test showed good sensitivity with minimal hands-on time. Technicians now have the ability to have flexible batch sizes which could make it the cost-effective choice for many hospital laboratories."

About the Roche LightCycler® MRSA Advanced Test

The LightCycler® MRSA Advanced Test is performed on Roche's LightCycler® 2.0 Instrument with nasal swab specimens from patients suspected of MRSA colonization. Offered in a convenient, ready-to-use format and designed for flexible batch sizes, the test is intended to help ensure the safety and productivity of laboratory staff and provides flexible throughput with accurate, reliable results. The combined capabilities of the LightCycler® 2.0 Instrument with the flexible design and reliable detection of the LightCycler® MRSA Advanced Test are intended to provide a versatile, cost-effective medically valuable tool to support healthcare institutions in their efforts to prevent and contain the spread of MRSA infection. Roche's LightCycler® 2.0 Instrument remains among the most widely used real-time amplification systems available worldwide.

About methicillin-resistant *Staphylococcus aureus* (MRSA)

Methicillin-resistant *Staphylococcus aureus* (MRSA) is a type of bacterium that is resistant to certain antibiotics, such as methicillin, oxacillin, penicillin and amoxicillin. *Staphylococcus aureus* is one of the most frequently isolated bacteria from patients with healthcare-associated infections (HAIs). Estimates suggest that 2 million HAIs and 90,000 deaths are attributable to these infections each year in the U.S., and that between 5% and 10% of inpatients in U.S. hospitals acquire an HAI.¹

Antimicrobial resistance and HAIs, either combined or separately, constitute a major infectious disease problem in the U.S. and show signs of becoming more prevalent in the future. MRSA infections are a tremendous burden for healthcare systems and hospitals and are associated with significant healthcare costs. In 2007, the Centers for Disease Control and Prevention (CDC) estimated that HAIs were responsible for \$4.5 to \$5.7 billion in added healthcare costs each year.¹ Experts generally believe that at least 20-30% of such infections are preventable, and molecular-based diagnostic tests to detect HAIs offer faster, sensitive methods to detect infections and prevent their spread. In the U.S. it is estimated that the market for molecular-based MRSA screening is estimated to be worth approximately \$125 million in 2010 and growing at 20% per annum.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2009, Roche had over 80,000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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¹ http://www.cdc.gov/ncidod/dhqp/pdf/hicpac/infections_deaths.pdf. Public Health Reports, March-April 2007. Accessed July 2009.