Media Release

Pleasanton, CA 27 November 2012

Roche Announces Expanded CE Mark Indication for cobas® 4800 HPV Test Supporting Its Use as a Primary Screen for Cervical Cancer

HPV DNA detection finds disease missed by Pap cytology

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announces an expanded CE mark indication for the **cobas®** 4800 HPV Test. The newly expanded indication for the **cobas®** 4800 HPV Test as a primary screen means Pap cytology is no longer required as a co- or pre-test in countries that accept a CE mark. Persistent infection with Human Papillomavirus is the principal cause of cervical cancer in women. The expanded indication is supported by data to be presented at the International Papillomavirus Conference, November 30-December 6, 2012 in San Juan, Puerto Rico.

"HPV testing provides a more sensitive level of screening than the Pap test. Whereas a Pap smear looks for abnormal cells, an HPV test looks for the presence of HPV DNA itself," says Eduardo Franco, director, Division of Cancer Epidemiology, McGill University, Montreal, Canada. "The prevalence of HPV means that many women may test positive, so it is important to also identify those most at risk to progress to cervical cancer. Genotyping for HPV types 16 and 18 provides sufficient additional specificity to identify the women most at risk, and spares the rest from potentially unnecessary intervention. The two HPV genotypes, 16 and 18, account for 70% of cervical cancer cases."

HPV DNA testing has more traditionally been used as a co-test or reflex test to an abnormal or borderline cytology result. While Pap screening has dramatically decreased the prevalence of cervical cancer over the past several decades, Pap cytology has limitations due to low sensitivity and the subjective nature of results interpretation. However, studies show that HPV DNA testing is more sensitive than the Pap smear in picking up disease – important in a front-line screen. In the landmark ATHENA study, it is shown that the **cobas®** 4800 HPV Test finds disease that is missed by cytology - 1 in 10 women who tested positive for either HPV genotypes 16 or 18 by the Roche **cobas®** 4800 HPV Test already had evidence of cervical pre-cancer, even though their Pap test was normal.

Approximately 275,000 women worldwide still die of cervical cancer each year, and many countries are in the process of piloting HPV DNA testing as a primary screening replacement for Pap cytology. "Switching towards use of the **cobas®** 4800 HPV Test as a first line screen enables countries to implement strategies that catch more disease with fewer medical

interventions, allows physicians to better manage their patients, and reduces economic costs to the healthcare system," said Paul Brown, Head of Roche Molecular Diagnostics.

The **cobas**®4800 HPV Test is the only clinically validated, and FDA-approved test, that simultaneously provides pooled results on known "high-risk" genotypes and individual results on the highest-risk genotypes, HPV 16 and HPV 18, giving three results in just one test. The **cobas**® 4800 HPV Test has a fully automated sample preparation workflow process, and unique efficiency features allowing for higher throughput, making it well suited for high volume screening programs.

"As an organization committed to women's health, Roche Diagnostics is dedicated to keeping women healthy and improving patient care", Paul Brown continued. "Combined with our products from the mtm business acquisition announced last year, Roche has a broad cervical cancer prevention portfolio which redefines cervical cancer screening and more effectively guides patient management decisions."

International Papillomavirus Conference

Roche will present data which supports the **cobas**® 4800 HPV Test expanded indication as well as the broader Roche cervical cancer portfolio at the International Papillomavirus Conference, November 30-December 6, 2012 in San Juan, Puerto Rico.

Roche Satellite Symposium: Translating Science into Primary Screening Practice
Monday, 3 December, 12:30 PM – 1:45 PM, Puerto Rico Convention Center, Ballroom B

Primary HPV screening: Impact of varying the age of initiation on the performance of screening
Wright TC, Cox JT, Sharma A, Apple R, Behrens CM
Tuesday, 4 December, 2:00PM - 3:30PM, Room 208

3 Year cumulative incidence rates for high-grade cervical disease: Interim analysis from the ATHENA study
Castle PE, Wright TC, Stoler, MH, Zhang, Behrens CM
Tuesday, 4 December, 2:00PM- 3:30PM, Room 208

Intra-laboratory variation in the performance of liquid-based cytology; insights from ATHENA
Stoler MH, Wright TC, Apple R, Sharma A, Behrens CM
Tuesday, 4 December, 5:30PM - 7:30PM (Poster Session)

About the ATHENA Study
Roche's landmark ATHENA study for the **cobas**® 4800 HPV Test is the largest U.S.-based registration study for cervical cancer screening, including more than 47,000 women.

About the cobas® 4800 HPV Test and cobas® 4800 System
The cobas® 4800 HPV Test is a qualitative in-vitro test for the detection of Human Papillomavirus in patient specimens. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies the high risk HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68), while simultaneously also detecting the highest risk types, HPV 16 and HPV 18. It is now available in the US and all countries accepting a CE mark.

The cobas® 4800 System is designed to deliver new standards in laboratory testing efficiency and medically relevant diagnostic information. The system offers true walk-away automation and can run up to 282 tests in less than 12 hours, providing rapid analysis of screening tests for HPV infections meeting the needs of the majority of clinical labs.

About Human Papillomavirus and Cervical Cancer
Persistent infection with Human Papillomavirus is the principal cause of cervical cancer in women, with HPV implicated in greater than 99 percent of cervical cancers worldwide. According to the National Cancer Institute, there are 12,200 new cases of cervical cancer in the United States annually and 4,210 deaths due to the disease. The World Health Organization estimates there are 470,000 new cases of cervical cancer annually.

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 2011, Roche had over 80,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 42.5 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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