Media Release

Pleasanton, CA 8 July, 2013

Roche submits filing to FDA for cervical cancer primary screening indication for cobas® HPV Test

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced it has submitted a Premarket Approval (PMA) supplement to the U.S. Food and Drug Administration (FDA) seeking the addition of a cervical cancer primary screening indication for the **cobas®** HPV Test. Approval of the expanded indication would mean the **cobas®** HPV Test could be used as the first-line test rather than Pap cytology as part of a cervical cancer screening strategy. The filing includes new three-year follow-up data from the ATHENA study, Roche's landmark U.S.-based registration trial, including more than 47,000 women screened for cervical disease with Pap and HPV (Human Papillomavirus) tests.

"This milestone demonstrates our long-term commitment to cervical cancer prevention and women's health," said Paul Brown, Head of Roche Molecular Diagnostics. "Our ATHENA study validates the value of HPV DNA detection and we are confident that these data will demonstrate to the FDA that we have established the clinical utility of the **cobas®** HPV Test in primary screening for physicians and their patients."

The **cobas®** HPV Test is the only FDA approved test that provides pooled results for known high risk genotypes and in addition, simultaneously provides individual results for the 2 highest risk genotypes, HPV 16 and HPV 18. Data from the ATHENA study published in the American Journal of Obstetrics & Gynecology in November 2012 by Cox et al. show strategies that incorporate high-risk HPV DNA testing with simultaneous detection of genotypes 16 and 18 as an initial screening test can detect more cervical disease than strategies that use Pap alone, representing significant potential benefits for patients.

The **cobas®** HPV Test received FDA approval in April 2011 to screen patients age 21 and older with abnormal Pap test results and to co-test with Pap in women ages 30 to 65 to assess the presence or absence of high-risk HPV genotypes. In November 2012, the test was also CE marked for use as a primary screening test in countries that accept the CE mark.

About the cobas® HPV Test and cobas® 4800 System
Clinically validated by the landmark ATHENA trial, the **cobas®** HPV Test is the only FDA-approved HPV assay that provides specific genotyping information for HPV 16 and 18, the highest-risk types, while simultaneously reporting the 12 other high-risk HPV types as a pooled result, all in one run, from one patient sample.

The test is performed on the **cobas®** 4800 system, which offers true walk-away automation of nucleic acid purification, PCR (polymerase chain reaction) set-up and real-time PCR amplification and detection to help laboratories achieve maximum efficiency. The system also runs the **cobas®** CT/NG Test (chlamydia/gonorrhea), the **cobas®** BRAF V600 Mutation Test and the **cobas®** EGFR Mutation Test.

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, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner 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 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. 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.

# # #

For media inquiries please contact:

888-545-2443