Media Release

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New Professional Guidelines Recognize Benefit of Genotyping HPV 16 and 18 for Cervical Cancer Prevention by Assessing Individual Patient Risk

Evidence to support DNA genotyping for HPV as a co-testing approach provided by Roche's landmark ATHENA study

Roche (SIX: RO, ROG; OTCQX: RHHBY) today welcomed new guidelines for the prevention and early detection of cervical cancer issued jointly by the American Cancer Society (ACS), the American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Society for Clinical Pathology (ASCP).

For the first time, these professional organizations together issued guidelines that using human papillomavirus (HPV) testing in addition to a Pap test (also known as co-testing) is preferable to using a Pap test alone for women ages 30 – 65 years. The recommendation for co-testing is based on evidence showing that adding an HPV test to cytology increases detection of cervical pre-cancer and reduces the rate of invasive cervical cancer, compared to using a Pap test alone. Co-testing in this age group is also supported as an alternative to Pap testing alone for women who wish to lengthen the screening interval by a newly updated statement of recommendations on Cervical Cancer Screening Guidelines issued by the U.S. Preventive Services Task Force (USPSTF).

Moreover, for the first time, all three professional societies also jointly recommend including HPV genotype testing for HPV 16 and 18 (the highest-risk types) to more fully assess patients' risk for cervical cancer. Specifically, the societies recommend that individual genotyping for HPV 16 or HPV 16 and 18 be used when women have a negative cytology (Pap test) but have positive results on a test for "pooled" high-risk HPV types. As an alternative for managing these patients, the guidelines continue to offer the option of repeating Pap and HPV testing at a one-year interval.

Roche's landmark ATHENA study is cited by the professional organizations as a central study providing the evidence for differential patient management based on HPV 16 and 18 DNA genotyping. This study showed that 1 in 10 women with normal cytology who were HPV 16+ and/or HPV 18+ had high-grade cervical disease that was missed by cytology.

The Roche ATHENA study for the cobas® HPV Test is the largest U.S.-based registration study for cervical cancer screening, including more than 47,000 women. The cobas® HPV Test is the only clinically validated, FDA-approved assay that simultaneously provides pooled results on high-risk genotypes and individual results on the highest-risk genotypes, HPV 16 and HPV 18, giving three results in just one test.

“Cervical cancer is effectively treated in its early stages and, as an organization committed to women’s health, Roche Diagnostics is dedicated to helping eliminate this disease and improve patient care”, said Paul Brown, Head of Roche Molecular Diagnostics.

“The ATHENA study showed clearly that women with normal cytology — a normal Pap result — could already have cervical pre-cancer and are at the highest risk if they are positive for genotype HPV 16 and/or 18. These two genotypes, 16 and 18, cause more than 70 percent of cervical cancer cases,” said Catherine Behrens, MD, PhD, Director, Clinical Research at Roche Molecular Systems and medical lead for the ATHENA study. “We are pleased that our ATHENA data were taken into consideration and served as a tool for the committees to make an informed decision.”

About the cobas® HPV Test and cobas® 4800 System

The cobas® 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 types HPV 16 and HPV 18 while concurrently detecting the other high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68). 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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