

Media Release

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FDA Advisory Committee Unanimously Recommends Roche's HPV Test as Primary Screening Tool for Detection of Women at High Risk for Cervical Cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) Microbiology Devices Panel of the Medical Devices Advisory Committee recommended unanimously that the benefits of the **cobas**[®]HPV (Human Papillomavirus) Test as a first-line primary screening tool in women 25 years and older to assess their risk of cervical cancer based on the presence of clinically relevant high-risk HPV DNA outweigh the risks. The panel also voted unanimously that the **cobas**[®]HPV Test is safe and effective for the proposed indication for use. If approved, the **cobas**[®]HPV Test would become the first and only HPV test indicated as the first-line primary screen of cervical cancer in the United States.

“Every year, 12,000 women are diagnosed in the U.S. with cervical cancer. This is especially tragic because cervical cancer is a largely preventable disease, and it is well established that HPV is the cause of almost all cervical cancers worldwide. Women need better access to screening tools that include primary HPV screening in order to reduce their risk of developing cervical cancer,” said Dr. Thomas C. Wright, Jr., Professor Emeritus of Pathology and Cell Biology, Columbia University Medical Center, NY. “I am pleased that the FDA panel recognized the importance of validated, scientific evidence documenting the use of primary HPV screening to detect women at risk of invasive cervical cancer and allow us to prevent cervical cancer from developing.”

HPV causes more than 99 percent of cervical cancers and HPV genotypes 16 and 18 cause 70 percent of these cases worldwide. For decades, women have relied on cytology to detect evidence of disease. The ATHENA study, which included more than 47,000 women, showed

that a significant number of women would benefit by using the **cobas**[®]HPV Test as primary screening for cervical cancer. In fact, ATHENA demonstrated that nearly 1 in 7 women with normal Pap cytology who were HPV 16 positive actually had high-grade cervical disease that was missed by cytology.

“Through technological and scientific advancement, we now have a better screening tool for cervical cancer. Women around the world deserve the best tool to know their risk and reduce their chances of developing cervical cancer,” said Roland Diggelmann, COO Division Roche Diagnostics. “We look forward to working with the FDA and medical community to support the growing understanding and awareness of the role that HPV plays in cervical disease, and the importance of the **cobas**[®]HPV Test, which provides the necessary medical benefit to become the first line test in a cervical cancer screening strategy. ”

The Committee's recommendation will be considered by the FDA in its review of the primary screening indication for the **cobas**[®]HPV Test. The FDA is not bound by the Committee's guidance, but takes its advice into consideration when reviewing medical devices.

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 **cobas**[®]HPV Test received FDA approval in April 2011 for screening patients age 21 and older with abnormal cervical cytology results and for use adjunctively with normal cervical cytology in women ages 30 and over to assess the presence or absence of high-risk HPV genotypes. Roche submitted their Premarket Approval (PMA) supplement for the cervical

cancer primary screening indication with the FDA in June 2013. The filing includes 3-year follow-up data from the ATHENA study, Roche's landmark U.S.-based registration trial. ATHENA enrolled more than 47,000 women who were screened for cervical disease and an impact analysis of screening algorithms was performed based on these data.

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 more than 12,000 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 more than 500,000 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, immunology, infectious diseases, ophthalmology 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 personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 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.

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