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## **A New Study Shows that Testing for HPV Genotypes 16 and 18 Detects Cervical Pre-Cancer Missed by Pap Test**

*1 in 10 women in the ATHENA trial, age 30-years and older, who tested positive for HPV genotypes 16 and/or 18 by the cobas® 4800 HPV Test had cervical pre-cancer, although their Pap test was normal*

*Involving more than 47,000 women, the ATHENA trial is the largest registration study ever conducted for cervical cancer screening*

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that data from the ATHENA (Addressing THE Need for Advanced HPV Diagnostics) U.S. registration trial of over 47,000 women demonstrate that two human papillomavirus genotypes, HPV 16 and HPV 18, can identify those women with cervical pre-cancer missed by cytologic examination with a Papanicolaou (Pap) test. In the trial, 1 in 10 women age 30-years and older, who tested positive for HPV genotypes 16 and/or 18 by the cobas® 4800 HPV Test had cervical pre-cancer, although their Pap test was normal. The data demonstrate the importance of HPV genotyping to increase the accuracy of assessing cervical cancer risk, especially by screening for the two highest risk HPV genotypes (16 and 18), and underscore the limitations of relying upon cytology (Pap) testing alone in identifying women with cervical pre-cancer. The data were presented today by Thomas C. Wright Jr., M.D. of Columbia University at the 26th International Papillomavirus Conference in Montréal, Canada.

“The ATHENA data show that women who are positive for HPV 16 and/or 18 should be directly referred for closer examination of the cervix by colposcopy,” said Dr. Wright. “Screening for high-risk HPV genotypes provides important additive information to Pap testing, and screening for the two highest risk types, HPV 16 and 18, should be included to provide predictive information about a woman’s risk for having cervical pre-cancer or cancer.”

Novel findings from the ATHENA clinical trial, show that women positive for HPV 16 and/or 18 with the cobas® 4800 HPV Test who had a normal Pap test were at the same risk of having cervical pre-cancer as women who tested positive for any of the 14 high-risk HPV types with an equivocal Pap test (ASC-US, Atypical Squamous Cells of Undetermined Significance). The latter clinical situation is broadly accepted to carry a risk of pre-cancer that warrants immediate investigation, underscoring the importance of testing for HPV genotypes 16 and 18 in women with normal Pap tests.

“ATHENA is a landmark trial demonstrating how state-of-the-art medical diagnostics can address the limitations of cervical cancer screening with Pap tests alone,” said Daniel O’Day, Chief Operating Officer for Roche Diagnostics. “If more women were tested for high-risk HPV genotypes, specifically genotypes 16 and 18, more cervical pre-cancer could be found and treated earlier. This would prevent progression to cancer and ultimately save lives.”

#### **About the Roche ATHENA Clinical Trial**

The Roche ATHENA trial for the **cobas**<sup>®</sup> 4800 HPV Test is the largest U.S.-based registration study of more than 47,000 women. The trial is designed to answer current medical and scientific questions about the importance of testing for high-risk HPV genotypes in cervical cancer screening and to provide clinical information about the specific HPV genotypes that put women at highest risk for developing cervical cancer.

#### **About the cobas<sup>®</sup> 4800 HPV Test and cobas<sup>®</sup> 4800 System**

As demonstrated in the ATHENA trial, the Roche **cobas**<sup>®</sup> 4800 HPV Test is the only HPV test under investigation in the U.S. that simultaneously detects 12 high-risk HPV types (HPV types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) as a pooled result, as well as HPV genotypes 16 and 18 individually.

Roche launched the **cobas**<sup>®</sup> 4800 HPV Test with CE Mark in 2009. The test is currently under review and pending Pre-Market Approval (PMA) by the FDA. The test is not currently available in the United States.

#### **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% of cervical cancers worldwide. Of the more than 118 different types of HPV, 13-16 types are currently considered high-risk for the development of cervical cancer and its precursor lesions. HPV types 16 and 18 have been identified as the highest risk genotypes, detected in approximately 70 percent of cervical cancers. Nucleic acid (DNA) testing is a sensitive and non-invasive method for determining the presence of a cervical HPV infection.

#### **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](http://www.roche.com).

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