Media Release

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Preliminary Data from Roche ATHENA Cervical Cancer Trial Support Value of Human Papillomavirus Genotyping

Roche Molecular Systems, Inc. (SIX: RO, ROG; OTCQX: RHHBY) announced today that preliminary data from its ATHENA (Addressing THE Need for Advanced HPV Diagnostics) trial support the importance of screening for human papillomavirus (HPV) genotypes that put women at highest risk for developing cervical cancer. ATHENA is a prospective, double-blind, multi-centered, 47,000-patient, U.S.-registration trial designed to demonstrate the effectiveness of HPV detection as part of a cervical cancer screening program. Thomas C. Wright Jr., M.D., of Columbia University presented the preliminary data on February 18 during the Genotyping session (Scientific Session 2) at the EUROGIN 2010 congress in Monaco.

"The findings to date from the ATHENA trial support the growing understanding that certain HPV genotypes are highly associated with the development of high-grade cervical intraepithelial neoplasia (CIN grade 2 or higher), a direct precursor to cervical cancer," said Dr. Wright.

Persistent infection with HPV is the principal cause of cervical cancer in women, with HPV implicated in greater than 99 percent of cervical cancers worldwide. Cervical cancer is a global public health problem, accounting for 10 percent of all cancers in women. While the Papanicolaou cytology smear (Pap smear) has reduced deaths from cervical cancer by 70 percent in developed countries, the Pap smear has demonstrated limited ability to detect cervical cancer and its pre-cancer lesions based on a single test result. As a result, physicians are increasingly using HPV DNA testing together with Pap smears to more precisely determine a woman's risk for developing cervical cancer.

"While significant progress has been made in screening for cervical cancer over the past 50 years, it is clear that testing for HPV DNA as part of a cancer screening program allows the identification of cancer and its precursors earlier than when Pap smear alone is used," said Teresa Wright, M.D., chief medical officer, Roche Molecular Diagnostics. "In HPV positive women 30 years and older with normal pap smears, current screening guidelines recommend testing for specific HPV genotypes to identify those with the highest risk for cancer and its precursors. The demonstrated cervical disease in women with HPV genotype 16 enrolled in ATHENA supports these recommendations."

About the Roche ATHENA Trial

The Roche ATHENA trial is designed to answer current medical and scientific questions about the importance of testing for human papillomavirus (HPV) genotypes in cervical cancer screening and to provide additional information about the specific HPV genotypes that put a woman at highest risk for developing

cervical cancer. The Roche ATHENA HPV trial enrolled 47,000 women and screened participants for cervical cancer using the Pap test and HPV DNA tests for 14 genotypes that are known to put women at high risk. All women with a positive HPV test and a positive Pap test in the trial were referred for further blinded investigation of whether they had cervical cancer or pre-cancerous disease.

As reported today, preliminary analysis of data from more than 8,000 women who underwent biopsy in the ATHENA trial demonstrated that those with HPV genotype16 had the highest rate of pre-cancer, also known as cervical intraepithelial neoplasia (high-grade CIN2 and CIN3+ lesions). In addition, HPV genotype 18 was associated with increased rates of CIN3+ disease, particularly in women 36 years and older. Data from the preliminary analysis also demonstrated that further evaluation of HPV genotypes associated with high-grade cervical disease may be warranted.

About Human Papillomavirus and Cervical Cancer

Of the more than 118 different types of HPV, 14 types are currently considered high-risk for the development of cervical cancer and its precursor lesions (types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68). Nucleic acid (DNA) testing is a sensitive and non-invasive method for determining the presence of a cervical HPV infection. Roche launched its DNA test, the cobas® 4800 HPV Test, with CE Mark in 2009. This test is not available in the United States.

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.

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