FDA Approves Roche’s HPV Test for Identifying Women at Highest Risk for Cervical Cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has approved the cobas HPV (Human Papillomavirus) Test which identifies women at highest risk for developing cervical cancer. This test will help physicians make early, more accurate decisions about patient care, which may prevent many women from developing this deadly disease.

The cobas HPV Test is the only FDA-approved cervical cancer screening test that allows HPV 16 and 18 genotyping concurrently with high-risk HPV testing. It individually identifies genotypes 16 and 18, the two highest-risk HPV genotypes responsible for more than 70 percent of cervical cancer cases, while simultaneously detecting 12 other high risk HPV genotypes. The approval was based on data from the ATHENA study involving more than 47,000 women in the US. Results demonstrated that 1 in 10 women, age 30 and older, who tested positive for HPV 16 and/or 18 by the cobas HPV Test actually had cervical pre-cancer even though they showed normal results with the Pap test.

“The FDA approval of the cobas HPV Test demonstrates the value of simultaneous HPV 16 and 18 genotyping in cervical cancer screening,” said Daniel O’Day, Chief Operating Officer of Roche Diagnostics. “We look forward to working with laboratories and physicians to introduce the cobas HPV Test into routine cervical cancer screening.”

More than 55 million Pap cytology (“Pap smear”) tests are performed in the US annually. Current guidelines for screening allow for either cytology or cytology plus HPV testing to determine the risk of cervical cancer. However, HPV testing, and 16 and 18 genotyping in particular, identifies more women at risk earlier than Pap cytology testing alone.

“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 can provide predictive information about a woman’s risk for having cervical pre-cancer or cancer,” said Mark H. Stoler, MD, Professor and Associate Director of Surgical Pathology and Cytopathology, at the University of Virginia Health System. “The cobas HPV Test provides physicians with a validated tool that helps them make early and more informed decisions regarding patient care.”

**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**

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