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FDA Approves Roche's HPV Test for First-Line Primary Screening for Cervical Cancer

Expanded indication makes cobas HPV Test the only test approved in U.S. that can be used instead of Pap in first-line primary screening in women 25 and older

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) approved the cobas HPV (Human Papillomavirus) Test for use as a first-line primary screening test for cervical cancer in women 25 and older. The approval follows the March 12 unanimous recommendation from the Microbiology Devices Panel of the FDA's Medical Devices Advisory Committee, making the cobas HPV Test the first and only HPV test in the United States approved for first-line primary screening.

"We are very pleased that the FDA has approved this test for first-line use in cervical cancer screening. It is a recognition for the value the cobas HPV Test provides to physicians and women to make more informed decisions that can ultimately prevent cervical cancer development," said Roland Diggelmann, COO Division Roche Diagnostics. "This is an outstanding example of how innovation in diagnostics is shifting the disease management paradigm to improve patient care and people's health. We are committed to working with the medical community and professional organizations to put the necessary clinical practice guidelines in place to encourage providers to incorporate this new screening strategy alternative in their patient protocols."

Prior to the approval of this additional claim, HPV tests had been used as a follow-up test for Pap (Papanicolaou) results and as an adjunct to Pap in women 30 years and older.

"Today's action by the FDA has given women a better alternative method to reassure themselves they do not have this deadly yet preventable disease," said Mark H. Stoler, MD, Professor (Emeritus) of Pathology and Clinical Gynecology at the University of Virginia Health System. "Using the cobas HPV Test as a primary screen means that women will have the opportunity to receive a better and more accurate standard of care. Clinically validated HPV screening detects the virus that causes cervical cancer and does a better job identifying women at risk than Pap testing alone. But most importantly, women found to be HPV negative

are provided a greater sense of security that they are safe from the disease.”

The cobas HPV Test provides both pooled high-risk HPV DNA results and individual detection of HPV 16 and HPV 18, the two types responsible for about 70 percent of cervical cancer. The FDA’s decision to approve the expanded use for the cobas HPV Test was based on results from the landmark ATHENA trial, which enrolled more than 47,000 women. The study demonstrated that one in four women who are HPV 16 positive will have cervical disease within three years and 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.

In addition, results from the ATHENA trial included a comparison of a cobas HPV Test screening strategy to alternative strategies using Pap cytology and HPV testing. The comparison showed that a strategy leveraging the ability of the cobas HPV Test to identify women testing positive for HPV 16 or 18, and using cervical cytology (Pap) as a triage, follow-up test, would allow clinicians to detect more disease without referring a significant number of women to unnecessary follow-up.

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 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. For more information on the cobas HPV Test, please visit www.hpv16and18.com

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

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