# Roche receives FDA approval for expanded use of the CINtec *PLUS* Cytology test to aid clinicians in preventing cervical cancer

- **Next-generation biomarker cytology test supports World Health Organization's goal to eliminate cervical cancer, which is nearly 100 percent preventable with proper screening, vaccination and treatment**
- **New indication allows this first FDA-approved biomarker-based test to be used as triage for positive cobas HPV tests run on cobas 6800/8800 Systems in primary screening or co-testing programs**
- **More sensitive than traditional Pap cytology, this test allows clinicians to determine which HPV-positive women require further diagnostic procedures to prevent disease progression**

Basel, 16 September 2020 — Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced U.S. Food and Drug Administration (FDA) approval for the expanded use of CINtec® *PLUS* Cytology, the first triage test based on biomarker technology for women whose cervical cancer screening results are positive for high-risk types of human papillomavirus (HPV). Additional information from this test supports clinical decisions about which women will benefit most from immediate follow-up. Laboratories can now use CINtec *PLUS* Cytology to triage positive results from the cobas® HPV Test run on the fully integrated, automated and high-throughput cobas® 6800/8800 Systems.

High-risk HPV is the principal cause of cervical cancer, which is one of the most common cancers in women globally. The World Health Organization has set goals for countries to take action to eliminate cervical cancer by 2030.

"With our portfolio of cervical cancer tests and automated testing platforms, we are committed to providing clinicians and laboratories with the best tools possible to protect women's health," said Thomas Schinecker, CEO Roche Diagnostics. "This expanded indication for CINtec *PLUS* Cytology gives laboratories the flexibility to triage cobas HPV test results on their choice of cobas® Systems and deliver accuracy needed to reliably detect HPV infections that are starting to cause cellular changes that could lead to cancer. The biomarker information helps to clarify a woman's risk of disease, reduce the potential for over- or under-treatment, and is a major step forward in individualising a woman's care."

HPV DNA screening identifies women at risk for cervical cancer by detecting the presence of high-risk HPV DNA in cervical samples. While most HPV infections resolve on their own, some women who test positive for the virus, or whose co-testing results are discrepant (HPV positive/Pap cytology negative), may have or may develop pre-cancerous cervical lesions. These lesions could progress to cervical cancer if left untreated.

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**About human papillomavirus and cervical cancer**
Persistent infection with high-risk human papillomavirus (HPV) is the principal cause of cervical cancer in women, with HPV implicated in greater than 99 percent of cervical cancers worldwide.[1] Cervical cancer is nearly 100 percent preventable with proper HPV vaccination, screening and treatment; expanding access helps reach more women in underserved communities where the disease burden is highest.[2,3] It can take 10 to 15 years or longer for cervical cancer to develop, so knowing a woman's individual risk and finding disease early, before cancer develops, is an important prevention strategy.

About 13,800 new cases of invasive cervical cancer will be diagnosed in the U.S. in 2020, according to the American Cancer Society, and about 4,290 women will die from the disease this year. Globally, the World Health Organization estimates there are more than 570,000 new cases of cervical cancer annually, and 311,000 deaths.[4] Learn more about the Roche Cervical Cancer Global Access Program.

**About CINtec *PLUS* Cytology**
The CINtec *PLUS* Cytology test detects the simultaneous presence within a single cell of the two biomarkers -- p16 and Ki-67. This abnormality is associated with HPV infections that are transforming and can, if left untreated, progress to pre-cancer or cancer. A positive result of these two biomarkers in a single cell signals that a woman is more significantly at risk for disease. The ability of CINtec *PLUS* Cytology to distinguish those women who are at higher risk for cervical disease provides labs, physicians and women, in conjunction with the clinician's assessment of patient screening history, other risk factors, and professional guidelines information, to guide patient management. Women with negative dual stain results are at significantly lower risk for cervical disease and their bodies can be given more time to clear HPV infection on their own. This could reduce the number and frequency of follow-up visits, saving some patients worry and time.

The CINtec *PLUS* Cytology test, which runs on the BenchMark ULTRA IHC/ISH system, is performed using the same sample that is used for HPV or liquid-based Pap cytology tests. This eliminates the need for additional or repeat sample collection or time spent waiting to find out if an infection is clearing.

For U.S. approval, the FDA considered data from the Roche-sponsored registrational IMPACT (IMproving Primary screening And Colposcopy Triage) trial, which enrolled approximately 35,000 women in the U.S. to clinically validate CINtec *PLUS* Cytology as a triage test in various screening scenarios. This latest expanded use approval gives laboratories access to the complete Roche Cervical Cancer Portfolio offering in the U.S., which includes the cobas HPV Test, CINtec *PLUS* Cytology and CINtec Histology. Depending on their workflow needs, labs now have the choice to fully automate their highest volume assays and utilise biomarker technology to offer more advanced, next-generation cytology solutions. Publication of the full IMPACT study findings is pending.

Prior to FDA approvals for its use for the triage of women who are HPV positive using the cobas HPV Test on the cobas® 4800 or cobas 6800/8800 Systems, the CINtec *PLUS* Cytology CE-IVD test had been used as a

triage test for HPV-positive results and mildly abnormal Pap cytology results in Europe, Asia, South America, Canada and Australia.

**About the Roche Cervical Cancer Portfolio**
The Roche Cervical Cancer Portfolio enables healthcare professionals to screen, triage and diagnose women, based on the confidence and clarity of results across a continuum of patient care. The unique combination of molecular, cellular cytology and tissue-based tests provides healthcare professionals powerful information to make patient care decisions and minimise unnecessary treatment. Along with cobas HPV for screening, and CINtec *PLUS* Cytology, CINtec Histology is used as an aid to confirm the presence of cervical disease in women who have had a tissue biopsy. CINtec Histology is the only FDA-cleared test that uses the p16 biomarker for a more conclusive diagnosis to provide distinctive visual confirmation of precancerous cervical lesions that may be missed by hematoxylin and eosin (H&E) interpretation alone. Like CINtec *PLUS* Cytology, CINtec Histology is also fully automated on the BenchMark IHC/ISH instruments.

**About the BenchMark ULTRA IHC/ISH system**
The BenchMark ULTRA system is a fully automated immunohistochemistry and in situ hybridization slide staining system, offering multiple features designed to provide diagnostic confidence to histopathology laboratories worldwide. With 30 independent slide drawers, the system gives histotechnologists continuous random access and supports single-piece workflow, which numerous studies have shown improves laboratory operational efficiency.

**About cobas Systems**
cobas HPV tests run on cobas Systems and are indicated for use for routine cervical cancer screening to assess the risk in women for cervical precancer and cancer as per professional medical guidelines, including primary screening, triage of ASC-US cytology and co-testing (or adjunctive screen) with cytology. These real-time PCR systems serve the areas of infectious disease, donor screening, sexual health, transplant, respiratory and antimicrobial stewardship. They are also part of the Molecular Work Area—a fully integrated laboratory workflow solution that empowers labs to significantly elevate their levels of efficiency, flexibility and scalability. When every moment matters, the fully automated cobas 6800/8800 Systems offer the fastest time to results with the highest throughput and the longest walk-away time available among automated molecular platforms. With proven performance, absolute automation and unmatched flexibility delivering unparalleled throughput 24/7—cobas 6800/8800 Systems are designed to ensure a lab's long-term sustainability and success … now, more than ever. Learn more now: www.cobas68008800.com.

**About Roche**
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the eleventh consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 billion. 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.



**References**

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