Media Release

Roche receives FDA approval for CINtec PLUS Cytology test to aid clinicians in improving cervical cancer prevention

- **Next-generation cytology test provides additional information for HPV-positive women who may have cervical pre-cancer**
- **More sensitive than Pap cytology testing when used as triage test for HPV-positive screening results, helping to improve the detection of cervical pre-cancer**
- **The first biomarker-based test specifically approved by the FDA to triage women with HPV-positive / Pap cytology-negative co-testing results, providing clinicians with a new option to guide patient management**
- **Launch supports the goal of the World Health Organization to eliminate cervical cancer, which is nearly 100 percent preventable**

Basel, 11 March 2020 — Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced US Food and Drug Administration (FDA) approval of CINtec® *PLUS* Cytology as the first biomarker-based triage test for women whose primary cervical cancer screening results are positive for the human papillomavirus (HPV) using the cobas® 4800 HPV Test. This biomarker technology simplifies clinical decision making by providing easy to understand results so that clinicians and women are clear on next steps.

The CINtec *PLUS* Cytology test identifies those women whose HPV infections are most likely to be associated with cervical pre-cancers. It enables clinicians to more confidently determine which women should be referred to immediate further diagnostic procedures, helping to prevent women from developing more advanced cervical disease.

About 13,800 new cases of invasive cervical cancer will be diagnosed in the US in 2020, according to the American Cancer Society, and about 4,290 women will die from the disease this year. Persistent infection with HPV is the principal cause of cervical cancer, with the virus implicated in more than 99 percent of cervical cancers worldwide.

“Despite being nearly 100 percent preventable, cervical cancer is still one of the most common cancers in women worldwide. To address this, Roche is dedicated to investing in next-generation biomarkers that will significantly advance screening strategies and support global efforts to eradicate this disease,” said Thomas Schinecker, CEO, Roche Diagnostics. “We are committed to providing women with the protection and care they deserve.” While most HPV infections resolve on their own, some women who test positive for the virus or whose co-testing results are inconclusive – HPV-positive and Pap cytology-negative – may develop pre-cancerous cervical lesions that, if left untreated, may progress to cervical cancer. Early identification of women who are most at risk is vital.

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CINtec *PLUS* Cytology provides definitive information about which HPV-positive women may benefit most from immediate referral to colposcopy versus repeat testing. This is a major step forward to individualize a woman's care and prevent both overtreatment and undertreatment.

FDA considered data from the Roche-sponsored registrational IMPACT (IMproving Primary screening And Colposcopy Triage) trial, which enrolled more than 35,000 women in the US to clinically validate CINtec *PLUS* Cytology as a triage test in different screening scenarios. Publication of study data is pending.

CINtec *PLUS* Cytology is expected to be widely commercially available in the US later in 2020.

About the CINtec *PLUS* Cytology test
The Roche cobas 4800 HPV Test, used in combination with CINtec *PLUS* Cytology and CINtec® Histology, offers clinicians and labs in the US powerful support they have not had before. The dual-stain biomarker technology included in 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, clinicians and women, in conjunction with the physician's assessment of patient screening history, other risk factors, and professional guidelines information, to guide patient management. This could reduce the number and frequency of follow-up visits, saving worry, time and money.

The new test can be performed using the same liquid sample that is used for HPV or Pap cytology testing. This eliminates the need for additional or repeat sample collection or time spent waiting to find out if an infection is clearing. Primary screening by the cobas 4800 HPV DNA test with triage using the CINtec *PLUS* Cytology test demonstrated the high sensitivity and specificity to detect transforming HPV infections reliably and cost-effectively.

Prior to FDA approval for use in the US, the CINtec *PLUS* Cytology test, which runs on the BenchMark ULTRA IHC/ISH system, had been used as a triage test for HPV-positive results and mildly abnormal Pap cytology results in Europe, Asia, South America and Australia.

About cobas® Systems
Based on Nobel prize-winning PCR technology, cobas Systems are designed to deliver full automation, increased throughput and faster turnaround time, providing users with greater flexibility to increase overall workflow efficiencies. The cobas® 4800 System® fully automates cobas® HPV sample preparation with real-time polymerase chain reaction (PCR) technology for amplification and detection. cobas Systems allow for consolidated assay menus for routine molecular testing in the areas of viral load monitoring, donor screening, women's health and microbiology. For more information about the systems, please visit www.diagnostics.roche.com.

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 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.

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