Media Release

Roche receives FDA approval for cobas HPV test for use on the cobas 6800/8800 Systems to identify women at risk for cervical cancer

- **More than 99 percent of cervical cancers are caused by persistent high-risk HPV infection[1]**
- **Cervical cancer is nearly 100 percent preventable with proper HPV vaccination, screening and treatment; expanding access helps reach more women[2,3]**
- **cobas 6800/8800 Systems deliver full automation, helping laboratories meet the throughput and efficiencies that high-volume, HPV DNA screening programs require**

Basel, 21 April 2020 - Roche (SIX: RO, ROG; OTCQX:RHHBY) today announced US Food and Drug Administration (FDA) approval for the cobas® HPV test for use on the fully automated, high-throughput cobas® 6800/8800 Systems. The cobas® HPV test identifies women at risk for cervical cancer by detecting the presence of high-risk human papillomavirus (HPV) DNA in cervical samples. Persistent high-risk HPV infections can develop into precancerous lesions and, if left untreated, these lesions can progress to cervical cancer.

"The approval of our HPV test for the cobas 6800 and 8800 Systems enables molecular laboratories to achieve the efficiency and scale they need to meet the demands of high-volume cervical screening programs," said Thomas Schinecker, CEO Roche Diagnostics. "This is critical as most healthcare providers in the US have adopted HPV testing as part of their cervical cancer screening protocol, with the ultimate goal of preventing cervical cancer in all women."

The goal of cervical cancer screening is to find and treat precancer early to help stop the progression of disease. The cobas HPV test helps to protect women from the potential harms of undetected and untreated cervical disease by detecting the virus that causes nearly all cervical cancers.

The cobas HPV test, previously approved for the cobas® 4800 System, is now part of the growing menu of clinically validated, FDA approved tests for use on cobas 6800/8800 Systems. Laboratories now have the ability to run HPV DNA tests simultaneously with other previously released cobas tests on these high-throughput systems.

The FDA considered data from the registrational IMPACT (IMproving Primary screening And Colposcopy Triage) trial, which enrolled almost 35,000 women in the US to clinically validate cobas HPV for use on the cobas 6800/8800 Systems. Study data will be broadly shared, pending publication of the key findings.

About cobas HPV test
cobas HPV is indicated for use for routine cervical cancer screening as per professional medical guidelines, including triage of ASC-US cytology, co-testing (or adjunctive screen) with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer.

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The cobas 4800 HPV Test, originally introduced in 2011 and supported by the ATHENA trial (Addressing the Need for Advanced HPV Diagnostics), helps healthcare providers identify women at risk for cervical cancer by individually identifying the presence of the DNA of HPV genotypes 16 and 18 – the two genotypes responsible for about 70 percent of all cervical cancers – and reporting the 12 other high-risk HPV types as a combined result, all in one test and from one patient sample. Roche received the first FDA approval to use an HPV test for primary cervical cancer screening without accompanying Pap cytology for the cobas HPV 4800 Test in 2014. More information about the cobas HPV tests is available at www.hpv16and18.com

About the Roche Cervical Cancer Portfolio
The Roche Cervical Cancer Portfolio enables healthcare professionals to better 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 and tissue-based tests provides healthcare professionals powerful information to make patient care decisions and minimize unnecessary treatment.

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, which was FDA approved in March 2020, 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.

CINtec Histology is the only FDA-cleared test used as an aid to confirm the presence of cervical disease in women who have had a tissue biopsy. The CINtec Histology test 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. Both CINtec assays are fully automated on the VENTANA BenchMark IHC/ISH instruments.

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. 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. Globally, the World Health Organization estimates there are more than 570,000 new cases of cervical cancer annually, and 311,000 deaths[4].

About cobas 6800/8800 Systems
Since 2014, the cobas® 6800 and cobas® 8800 Systems have established the new standard for routine molecular testing by delivering fully integrated, automated solutions that serve the areas of viral load monitoring, donor screening, sexual health and microbiology. Like the cobas 4800 System, each system is based on Nobel Prize-

winning polymerase chain reaction (PCR) technology. The cobas 6800/8800 Systems deliver proven performance with full automation, increased throughput, fast turnaround time and complete track connectivity validated for molecular testing, providing users with greater flexibility to consolidate their in vitro diagnostic (IVD) and laboratory developed testing (LDT) to a single system while increasing overall workflow efficiencies.

The cobas 6800/8800 Systems menu for sexual health includes Chlamydia trachomatis/ Neisseria gonorrhoeae (CT/NG),Trichomonas vaginalis/ Mycoplasma genitalium (TV/MG), and Herpes simplex virus (HSV-1, HSV-2). Additionally, the broad and expanding menu covers other infectious diseases such as a Mycobacteria assay portfolio, Hepatitis B and C (HBV and HCV), Human immunodeficiency virus (HIV), and Cytomegalovirus (CMV). For more information about the tests and systems, please visit www.diagnostics.roche.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

[1] Walboomers JM, Jacobs MV, Manos MM, et al. Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. J Pathol. 1999; 189:12-19.
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[3] Bosch FX, Broker TR, Forman D, et al. Comprehensive control of human papillomavirus infections and related diseases. Vaccine.

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[4] World Health Organization, www.who.int/health-topics/cervical-cancer#tab=tab_2

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