Media & Investor Release

Roche awarded WHO prequalification for the cobas® HPV test, increasing access to cervical cancer screening tools in low and lower-middle income countries

- **Every year, over 600,000 women worldwide are diagnosed with cervical cancer and over 340,000 die from this preventable disease, caused by infection with human papillomavirus (HPV). Nine out of 10 women who die from cervical cancer live in low- and lower-middle income countries (LMICs).[1]**
- **WHO prequalification enables LMICs to use the cobas® HPV test in their national cervical cancer elimination programs, increasing access to the patients who need it most.**
- **Establishing screening programs helps prevent and detect cervical cancer, which is especially important in areas with limited healthcare resources where patients are often diagnosed with the disease at late stages.**

Basel, 13 June 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the cobas® HPV test for use on the cobas® 6800/8800 Systems has been awarded World Health Organization (WHO) prequalification. WHO prequalification expands the availability of this critical HPV screening tool in countries that rely on the global organisation's list in making purchasing and implementation decisions.

Screening for Human Papillomavirus (HPV) can help identify women who are at risk of developing cervical cancer, so that the disease can be treated early, before invasive cancer has a chance to develop. In poorer countries, women are often diagnosed with cervical cancer at a more advanced stage, where the opportunity for a cure is low.

"The elimination of cervical cancer is within reach. Roche is committed to working with governments, non-profit organisations and funders to help build sustainable cervical cancer elimination programs so that women, no matter where in the world they live, no longer die from this preventable disease," said Matt Sause, CEO of Roche Diagnostics. "Today's action, combined with our recently-launched HPV-self sampling solution, further expands access to HPV screening in countries with limited healthcare resources."

The WHO strategy for global elimination of cervical cancer lists the following three target goals to reach by 2030[2]:

- 90% of girls should be fully vaccinated with HPV vaccine by 15 years of age;
- 70% of women should be screened using a high-performance test by age 35, and again by age 45;
- 90% of those identified with cervical disease should receive appropriate treatment.

The cobas® HPV test is already part of the Roche Global Access Program, which aims to improve access to cost-effective resources, implement scale-up programs, and contribute to the elimination of diseases in the regions with the greatest need. WHO prequalification helps expand that access and provides healthcare professionals with greater confidence that their clinical decisions will be based on accurate, reliable results.

About the Global Access Program

In 2014, Roche first launched its Global Access Program to support the UNAIDS 2020 targets to address the HIV/AIDS epidemic. Since then, the program was expanded to include solutions for other high-burden diseases such as Tuberculosis, Hepatitis B and C, and cervical cancer. Most recently, in response to the COVID-19 pandemic, the SARS-CoV-2 test was included into the program.

The continual expansion of test offerings highlights Roche's commitment to eliminate cervical cancer and other high burden infectious diseases for patients living in resource-constrained settings with limited access.

Any laboratory that implements a Roche instrument system gains the ability to scale up testing across multiple disease areas, thus improving cost and resource efficiency. An integrated approach supports national programs focused on increasing access to diagnostic testing, to help manage or reduce the impact of preventable disease for patients.

About the cobas HPV test

The cobas® HPV test is indicated for use for routine cervical cancer screening as per professional medical guidelines, including HPV primary screening, co-testing (or adjunctive screen) with cytology, and for triage of women with abnormal cytology, to assess the risk for cervical precancer and cancer. The cobas® HPV test detects the high-risk HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.

In June 2022, Roche further improved access for women when it launched an HPV self-sampling solution in countries accepting the CE mark. The solution enables a patient to privately and confidently collect her own sample following instruction from a healthcare worker. The clinically-validated vaginal sample is then analysed with the Roche cobas® HPV test on a Roche molecular instrument.

Cervical cancer screening using the cobas® HPV test is clinically validated in large, FDA registrational trials for use on cobas® Systems, and the assay individually identifies 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. More information about the cobas® HPV tests is available at diagnostics.roche.com/cervicalcancer.

The fully automated cobas® 6800/8800 Systems offer the fastest time to results, providing up to 96 results in about three hours and 384 results for the cobas® 6800 System and 1,056 results for the cobas® 8800 System in an eight hour shift. Learn more: diagnostics.roche.com.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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] World Health Organization. Cervix uteri. Fact sheet [Internet; updated 2021 January; cited 2023 Jan 3] Available from: https://gco.iarc.fr/today/data/factsheets/cancers/23-Cervix-uteri-fact-sheet.pdf
[2] World Health Organization. Global strategy to accelerate the elimination of cervical cancer as a public health problem. Article [Internet; updated 2020 November 17; cited 2023 Jan 3] Available from: https://www.who.int/publications/i/item/9789240014107

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