Media Release

Roche expands access to cervical cancer screening tools with two new WHO prequalification designations, including HPV self-collection

- **The World Health Organization (WHO) has awarded Roche's human papillomavirus (HPV) test prequalification designations for use on the cobas 5800 System and for self-collected samples on the cobas 5800, 6800 and 8800 Systems.**
- **These designations build upon last June's WHO prequalification that included the cobas HPV test for use on the cobas 6800 and 8800 Systems.**
- **WHO prequalification enables low- and middle-income countries (LMICs) to use Roche HPV screening solutions, including self-collection, in their national cervical cancer elimination programs, which will greatly increase access.**
- **Every year, over 600,000 women worldwide are diagnosed with cervical cancer and over 340,000 die from this preventable disease, caused by HPV infection. Nine out of 10 women who die from cervical cancer live in LMICs.[1]**

Basel, 27 June 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the World Health Organization (WHO) has awarded the cobas® HPV test prequalification designations for use on the cobas® 5800 system and for self-collected samples on the cobas® 5800, 6800 and 8800 systems. These new prequalification designations come just one month after the U.S. Food and Drug Administration approved Roche's HPV self-collection solution and less than a year after the WHO awarded prequalification to the cobas HPV test on the cobas 6800/8800 systems.

"No woman in the world should die from this preventable disease. These new prequalification designations for our cobas HPV test will create strong momentum in the fight to eliminate cervical cancer," said Matt Sause, CEO of Roche Diagnostics. "Countries that use the WHO list to make decisions on how to implement national screening programs can now leverage self-collection to further increase access."

The WHO is focused on the elimination of cervical cancer globally with a strategy of three key goals.[2] It seeks to ensure that by 2030, 70% of women are screened using a high-performance test by age 35, and again by age 45. Screening for HPV can help identify women who are at risk of developing cervical cancer, so that the disease can be treated early, before cancer has a chance to develop. In poorer countries, women are often diagnosed with cervical cancer at a more advanced stage, where the chance for a cure is low. The WHO also seeks to ensure that 90% of girls are fully vaccinated against HPV by 15 years of age, and that 90% of those identified with cervical disease receive appropriate treatment.

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The cobas HPV test prequalification designations from the WHO help expand access and provide healthcare professionals with greater certainty that their clinical decisions will be based on accurate, reliable results.

Fighting cervical cancer

Roche partners with health systems and governments in more than 55 countries to support their cervical cancer screening programs with the cobas HPV test. As a result of these collaborations, more women have been accessing HPV molecular testing. For example, after just one year of Roche and the Perúvian Ministry of Health working together with other government organisations and patient advocates, more than 300,000 unscreened or underscreened women, some in remote areas of the Amazon rainforest, have been tested for HPV using Roche's self-collection solution as the primary strategy to expand access.

The cobas HPV test is also 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.

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 has 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 eliminating 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 Roche Cervical Cancer Portfolio

HPV is the known cause of more than 95% of all cervical cancers.[2] Roche's cervical cancer portfolio includes the cobas HPV test, used for primary screening and co-testing. While the Pap smear can potentially detect abnormalities in the cervix, cobas HPV detects 14 types of high-risk HPV genotypes that put patients at higher risk of developing cervical cancer. It includes results for HPV 16, HPV 18 and 12 other high-risk pooled genotypes.[3]

The HPV self-collection solution is approved for use with Roche's cobas HPV test. The cobas HPV test runs on the cobas 4800 and the fully automated cobas 5800/6800/8800 Systems, which offers 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. The portfolio also includes CINtec PLUS Cytology, the only FDA-approved dual-stain product and CINtec® Histology, the only FDA-cleared p16 biomarker technology that can help pathologists confirm the presence of pre-cancerous cervical lesions.

The IMPACT trial design, used to validate the clinical benefits of the Roche cervical cancer portfolio, had representation from diverse patient segments, including 21 percent Black, 24 percent Hispanic-Latino and 0.3 percent American Indian or Alaskan Native participants.[4] This diversity was critical to accurately assess the performance of dual stain in patient populations with higher incident rates of HPV. Learn more now: http://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 endeavour 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 fifteenth 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

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