Media Release

WHO endorses dual-stain cytology (CINtec PLUS) testing in its cervical cancer prevention guidelines, advancing patient care and underlining Roche's role in pioneering cervical cancer solutions

- **Roche's CINtec PLUS Cytology is the only FDA-approved and CE-marked dual-stain test to triage human papillomavirus (HPV)-positive cervical cancer screening test results**
- **Dual-stain biomarkers aid in detection of cervical precancer and may reduce the number of women who undergo unnecessary colposcopy procedures while allowing earlier intervention for those who are at higher risk of developing cervical cancer.**
- **This recognition follows the American Society for Colposcopy and Cervical Pathology (ASCCP)'s recent inclusion of dual-stain testing in cervical cancer screening guidelines, as well as other WHO prequalifications of Roche's cobas HPV test**

Basel, 23 September 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the World Health Organization (WHO) has included dual-stain cytology testing in its cervical cancer prevention guideline.[1] The Roche CINtec® PLUS Cytology test is the only FDA-approved and CE-marked dual-stain test that helps identify human papillomavirus (HPV)-positive individuals who are most at risk of developing cervical precancer and cancer.

The WHO joins the American Society for Colposcopy and Cervical Pathology (ASCCP), which in March also updated its cervical cancer screening guidelines[2] to include dual-stain as a triage test for HPV-positive individuals. If the dual-stain test is positive, the patient is at higher risk of having or developing precancer or cancer, and clinicians should recommend immediate colposcopy. However, if the dual-stain test is negative, the risk of precancer is low and individuals may follow up by retesting at a later time to determine if their body has taken care of the infection and eliminated the risk on its own. This may result in fewer women unnecessarily undergoing colposcopy procedures.

"Adding dual-stain cytology to the WHO guidelines further reinforces the value of our biomarker-based CINtec PLUS Cytology test to identify patients with an elevated risk of cervical cancer," said Matt Sause, CEO of Roche Diagnostics. "HPV infections can cause cervical cancer, a potentially deadly disease that is highly preventable. Consequently, it is critical to determine who is most at risk."

The CINtec PLUS Cytology test can simultaneously detect when two biomarkers (p16 and Ki-67) are present within the same cell – a strong indicator that it is undergoing transformation and may turn cancerous. By identifying those individuals who are at higher risk of developing

cervical disease, CINtec PLUS Cytology helps provide labs, clinicians and patients with important information to guide patient management. This could reduce the number and frequency of follow-up visits, saving worry, time and money. The test can be performed using the same liquid sample that is used for HPV or Pap cytology testing, eliminating the need for additional or repeat sample collection.

The revised WHO guidelines represent an important step forward in achieving the organisation's three cervical cancer elimination goals[3], and a catalyst for ensuring that 90% of those identified with cervical disease receive appropriate treatment. With the recent news that the WHO has awarded prequalification designation to the cobas® HPV test on the cobas 4800, Roche's entire portfolio of HPV tests on the 4800, 5800, 6800 and 8800 systems is now WHO prequalification-approved for both clinician-collected and self-collected samples.

About the Roche Cervical Cancer Portfolio

HPV is the known cause of more than 95% of all cervical cancers.[4] Roche's cervical cancer portfolio includes the cobas HPV test, used for primary screening and co-testing. While Pap cytology 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 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. The portfolio also includes CINtec PLUS Cytology, the only FDA-approved dual-stain cytology product and CINtec Histology, the only FDA-cleared p16 biomarker technology that can help pathologists confirm the presence of pre-cancerous cervical lesions. The CINtec PLUS Cytology test can run on the BenchMark ULTRA IHC/ISH system. In countries accepting the CE mark, the CINtec PLUS Cytology test can be used to triage HPV-positive results.

The IMPACT trial, used to validate the clinical performance 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.[5] This diversity was critical to accurately assess the performance of the cobas HPV test and dual stain cytology in patient populations with higher incident rates of HPV. Learn more now: http://diagnostics.roche.com.

Roche is piloting a disease management software called navify® Cervical Screening. It aims to support health systems to increase adherence to clinical guidelines, reduce under- and over-testing and optimise healthcare resources with an organised approach to screening.

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.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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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