Media Release

Roche announces FDA approval of one of the first HPV self-collection solutions in the U.S., expanding access and screening options to help eliminate cervical cancer

- **More than half of all U.S. cervical cancer patients are underscreened[1], which makes reducing barriers to sample collection and increasing access to screenings crucial to ultimately helping eliminate this deadly disease.**
- **Each year in the U.S., more than 13,000 patients are diagnosed with cervical cancer and approximately 4,000 die from this preventable disease, caused by HPV infection.[1]**
- **Roche's human papillomavirus (HPV) self-collection solution will improve access to testing by providing women the option to privately collect their own sample.**

Basel, 15 May 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the FDA approval of its human papillomavirus (HPV) self-collection solution, one of the first available in the United States. Screening for HPV can help identify women who are at risk of developing cervical cancer so that the disease can be found and treated early before cervical cancer has a chance to develop.

HPV self-collection offers an accessible screening option. In a healthcare setting, an individual collects their own vaginal sample, which is sent to a laboratory for analysis with Roche's cobas® molecular instrument. Those who receive a positive HPV result would then continue their care with a healthcare provider.

"With vaccinations, innovative diagnostic tools and screening programs, achieving the WHO's goal of eliminating cervical cancer by 2030 is within reach," said Matt Sause, CEO of Roche Diagnostics. "Our HPV self-collection solution helps support this goal by reducing barriers and providing access to HPV screening by allowing people to privately collect their own sample for HPV testing."

More than half the patients diagnosed with cervical cancer in the U.S. have never been screened or have only been screened infrequently, and they do not participate in routine screening.[1] Many factors can contribute to individuals not participating in cervical cancer screening programs, such as access to healthcare, social and economic barriers, history of traumatic experience, cultural concerns and embarrassment. Roche's self-collection solution can help reduce these barriers by offering an alternative to clinician collection procedures, while also providing accurate and reliable results enabling clinicians to make patient care decisions.

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

Roche has collaborated with the National Cancer Institute (NCI), which is part of the National Institutes of Health (NIH), on the Cervical Cancer "Last Mile" Initiative. This public-private partnership has, in part, facilitated the regulatory pathway towards the approval.

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, the cobas HPV test detects 14 types of high-risk HPV genotypes that put patients at higher risk of 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

[1] https://deainfo.nci.nih.gov/advisory/joint/1219/Sahasrabuddhe.pdf
[2] WHO cervical cancer fact sheet
[3] cobas® HPV test [package insert]. Branchburg, NJ: Roche Molecular Systems, Inc.; 2020.
[4] Safaeian M, Wright TC Jr, Stoler MH, Ranger-Moore J, Rehm S, Aslam S, Fang Q, Volkir P, Ridder R. The IMproving Primary Screening And Colposcopy Triage trial: human papillomavirus, cervical cytology, and histopathologic results from the baseline and 1-year follow-up phase. Am J Obstet Gynecol. 2021 Sep;225(3):278.e1-278.e16. doi: 10.1016/j.ajog.2021.03.047. Epub 2021 Apr 20. PMID: 33852886

Roche Global Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 79 407 72 58

Nathalie Altermatt
Phone: +41 79 771 05 25

Karsten Kleine
Phone: +41 79 461 86 83

Kirti Pandey
Phone: +49 172 6367262

Dr. Rebekka Schnell
Phone: +41 79 205 27 03

Sileia Urech
Phone: +41 79 935 81 48

Simon Goldsborough
Phone: +44 797 32 72 915

Nina Mählitz
Phone: +41 79 327 54 74

Yvette Petillon
Phone: +41 79 961 92 50