

IMPACT trial data shows clear benefit in using Roche's CINtec PLUS Cytology test for women who are at higher risk of developing cervical cancer

- Every year, over 604,000 women worldwide are diagnosed with cervical cancer and approximately 342,000 die from this preventable disease, caused by Infection with high-risk human papillomavirus (HPV).
- As recently published in the International Journal of Cancer, the IMPACT (IMproving Primary screening And Colposcopy Triage) trial demonstrated that Roche's CINtec PLUS Cytology, when used as a triage test for high-risk HPV, showed a significantly higher sensitivity in detecting cervical pre-cancers in HPV-positive women compared to Pap cytology.
- It is the first FDA-approved dual-stain biomarker technology available for clinicians to guide decision-making based on individual patient risk, with the goal of helping to eliminate cervical cancer.

Basel, 29 October 2021 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that results from the IMPACT (IMproving Primary screening And Colposcopy Triage) trial demonstrate clear patient benefit in using Roche's CINtec PLUS Cytology dual-stain biomarker technology as a triage test for women who test positive for high-risk human papillomavirus (HPV). The data from the trial, established from a study cohort of more than 35,000 women aged 25-65 years, was published recently in the International Journal of Cancer.¹

In the IMPACT trial, women who were positive for high-risk HPV received a follow-up triage test to help determine if their cervical cells were transforming to cervical pre-cancer. The biomarker-based CINtec PLUS Cytology test showed a significantly higher sensitivity in detecting cervical pre-cancers, compared to Pap cytology. The Roche test aids clinicians in more confidently determining which women are at increased risk for high-grade cervical pre-cancer and require immediate further diagnostic procedures, and which women may need repeat testing or routine screening.¹

Over 604,000 women are diagnosed with cervical cancer worldwide each year and approximately 342,000 die from the disease.² Persistent infection with high-risk HPV is the principal cause of cervical cancer, implicated in more than 99 percent of cases worldwide.³ Cervical cancer is nearly 100 percent preventable with proper HPV vaccination, screening and treatment.

“As we approach the one-year anniversary of the World Health Organization's global strategy to accelerate the elimination of cervical cancer, Roche is committed to investing in and leading efforts such as the IMPACT trial to bring forth clinically validated solutions for women,” said Thomas Schinecker, CEO Roche Diagnostics. “The elimination of cervical cancer is within reach, and all countries must act now so that women, no matter where in the world they live, no longer die from this preventable disease. Our investment in HPV primary screening and next-generation biomarker technology gives clinicians even more powerful tools in the fight against cervical cancer.”

"These latest results from the IMPACT trial confirm data from previous studies that show incorporating the CINtec PLUS Cytology test in cervical cancer screening programs can provide real benefits to both clinicians and their patients," says Dr. Thomas Wright, Professor Emeritus in Pathology and Cell Biology at Columbia University Medical Center, New York. "As a triage test for HPV-positive cervical cancer screening results, the CINtec PLUS Cytology test can be very useful to differentiate women who will benefit most from immediate referral to colposcopy from those women who can be followed up with less invasive methods."

About Cervical Cancer and the IMproving Primary screening And Colposcopy Triage (IMPACT) Trial

Cervical cancer is nearly 100 percent preventable with proper HPV vaccination, screening and treatment. More than 604,000 new cases of cervical cancer are diagnosed each year worldwide. In 2020, cervical cancer was responsible for 7.7 percent of all female cancer deaths.^{2,4}

The landmark IMPACT trial was a prospective observational cervical cancer screening clinical study that enrolled approximately 35,000 women aged 25-65 years who were undergoing routine cervical cancer screening at 32 clinical sites in 16 states across the US. The study provides validation for the clinical utility of cobas HPV testing for primary screening in combination with CINtec PLUS Cytology as a follow-up test for patients with positive screening results.

The study showed that triaging with CINtec PLUS Cytology may lead to significantly improved detection of cervical disease when women are screened for cervical cancer. Cervical screening helps identify women at risk for disease before invasive cancer develops. While most HPV infections resolve on their own, some women who test positive for the virus may develop pre-cancerous cervical lesions that, if left untreated, may progress to cervical cancer. Early identification of women who are most at risk is vital.

In the study, HPV-positive women with CINtec PLUS Cytology negative triage test results showed a very low cumulative 1-year risk for disease, which was significantly lower than the risks associated with a negative Pap cytology triage test result in HPV-positive women.

Based on the results of the IMPACT trial, the FDA approved the CINtec PLUS Cytology test to be used as triage for positive HPV test results using cobas HPV on cobas 4800, 6800 and 8800 Systems in primary screening or co-testing programs.

Recommended clinical guidelines have also been evolving in favor of HPV tests for primary screening, supported by an interest to improve outcomes and the availability of technologies to help laboratories achieve the efficiency and scale they need to meet the demands of high-volume cervical screening programs.

About CINtec PLUS Cytology

The CINtec PLUS Cytology test 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 a higher risk for cervical disease, in conjunction with the clinician's assessment of patient screening history and other risk factors, provides labs, physicians and women with the information needed to guide patient management. Women with negative dual-stain results are at significantly lower risk for cervical disease and their bodies can be given more time to clear the HPV infection on their own. This could reduce the number and frequency of follow-up visits, saving some patients worry and time.

The CINtec PLUS Cytology test, which runs on the BenchMark ULTRA IHC/ISH system, is performed using the same sample that is used for HPV or liquid-based Pap cytology tests. This eliminates the need for additional or repeat sample collection or time spent waiting to find out if an infection is clearing.

CINtec PLUS Cytology, now available globally, was FDA approved in March 2020.

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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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 twelfth 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 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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.

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Roche Group Media Relations

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

Dr. Nicolas Dunant
Phone: +41 61 687 05 17

Patrick Barth
Phone: +41 61 688 44 86

Dr. Barbara von Schnurbein
Phone: +41 61 687 89 67

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mährlitz
Phone: +41 79 327 54 74

Nathalie Meetz
Phone: +41 61 687 43 05

Sileia Urech
Phone: +41 079 935 81 48

Roche Investor Relations

Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

Jon Kaspar Bayard
Phone: +41 61 68-83894
e-mail: jon_kaspar.bayard@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Investor Relations North America
Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com