Media Release

Roche receives China Food and Drug Administration (CFDA) approval for the CINtec® PLUS Cytology test to help prevent women from developing cervical cancer

Immunocytochemistry assay effective in identifying women with cervical pre-cancer

Tucson, AZ, March 8, 2016 - Roche (SIX: RO, ROG; OTCQX:RHHBY) announced the China Food and Drug Administration (CFDA) approval of the CINtec® PLUS Cytology test, designed to improve the detection and early intervention of pre-cancerous cervical disease.

A multi-center study of five participating hospitals throughout China revealed greater overall performance of combined sensitivity and specificity of the CINtec® PLUS Cytology test in determining which women are at higher risk of developing cervical cancer when compared to conventional screening methods like Pap cytology. This is consistent with previously published data and supported the approval of the test by the CFDA.

Virtually all cervical cancer is caused by human papillomavirus (HPV) infections, but only women with persistent HPV infections who have developed high-grade pre-cancerous cervical disease should be treated. The CINtec® PLUS Cytology test was developed to detect two biomarkers associated with persistent HPV infections that may lead to cancer, distinguishing them from those that are likely to resolve on their own.

About 62,000 new cases of cervical cancer are reported annually in China, and about 30,000 women in China die from the disease every year.

"With the launch of the fully automated CINtec® PLUS Cytology test, we can offer women in China the most comprehensive cervical cancer screening portfolio in the industry, thus fulfilling our commitment of preventing these women from developing cervical cancer," said Wong Fatt Heng, General Manager, Roche Diagnostics China. "The CINtec® PLUS Cytology test helps reduce over-diagnosis and improves the detection of pre-cancerous cervical disease, allowing early intervention."

"The CINtec® PLUS Cytology test is a powerful technology in the fight against cervical disease and is an important component of the Roche cervical cancer prevention portfolio," said Ann Costello, Head, Roche Tissue Diagnostics. "Human papillomavirus is the known cause of cervical cancer and is highly preventable. Now that a full range of Roche’s clinically-validated cervical cancer products—the cobas® HPV Test for screening, CINtec PLUS Cytology and CINtec Histology for triage and diagnosis—are approved by the CFDA, our ability to impact the burden of this disease on a global scale is dramatically increased."
Now available in China, Europe, Asia, Latin America and Canada, the fully automated CINtec® PLUS Cytology test can be performed using the company’s network of more than 10,000 diagnostic instruments installed worldwide.

1 World Health Organization Fact Sheet 380, September 2013: http://www.who.int/mediacentre/factsheets/fs380/en/
2 Globocan 2012: http://globocan.iarc.fr/Pages/fact_sheets_population.aspx

About the Roche cervical cancer screening portfolio

For screening, the cobas® HPV Test simultaneously provides results on high-risk human papillomavirus (HPV) DNA genotypes with individual results on the highest-risk genotypes, HPV 16 and HPV 18. The CINtec® PLUS Cytology test helps identify underlying disease, determining those who should proceed to colposcopy. The CINtec® p16 Histology test helps pathologists confirm the presence or absence of cervical pre-cancers in biopsies obtained during colposcopy.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives.

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. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine 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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 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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