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Roche announces launch of cobas HPV on the cobas 6800/8800 Systems for cervical cancer screening in markets accepting the CE mark

- **More than 99 percent of cervical cancers are caused by a persistent high-risk HPV infection¹**
- **cobas HPV assay helps to provide critical screening in identifying women at risk, before pre-cancer or cancer develops**
- **cobas 6800/8800 Systems deliver full automation, helping laboratories meet the throughput that high volume, HPV DNA screening programs demand**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the CE-IVD launch of cobas[®] HPV for use on the cobas[®] 6800/8800 Systems for cervical cancer screening. Human Papillomavirus (HPV) is a known cause of cervical cancer and is used to identify women at risk. This HPV DNA assay adds to the growing CE-IVD menu on the cobas 6800/8800 Systems, and gives laboratories the ability to run HPV DNA testing simultaneously with other previously released cobas assays including: Chlamydia and Gonorrhea (CT/NG), HIV-1, HCV, HBV, CMV, plus three next-generation assays for donor screening: cobas[®] MPX, cobas[®] WNV and cobas[®] HEV.

As demonstrated by the prospective clinical study “ATHENA” comparing screening strategies using cobas HPV test on the cobas[®] 4800 System, screening with the HPV test detects more high-grade disease than a Pap test alone. Identifying women at risk, before pre-cancer or cancer develops, is an important prevention strategy as it helps maintain screening efficiency and helps protect women from the potential harms of overtreatment. Countries are increasingly looking to adopt HPV DNA screening ahead of Pap cytology as part of their national cervical cancer programs.

“In addition to the powerful clinical benefits of the cobas HPV test, Roche now caters to the needs of both low-to-mid volume labs and high-throughput labs who want to consolidate a multitude of validated assays onto a single platform,” said Roland Diggelmann, CEO Roche Diagnostics. “As laboratories look toward the future, they require systems that provide the highest performance standards that Roche delivers as well as new ways to increase efficiency, which ultimately benefit everyone receiving or providing health care.”

The fully automated cobas 6800/8800 Systems provide the fastest turn-around time, highest throughput and the longest walk-away time compared to other automated molecular platforms, giving laboratories the flexibility to adapt to changing testing demands.

About the Roche Cervical Cancer Portfolio

The Roche Cervical Cancer Portfolio enables healthcare professionals to better screen, manage and diagnose women, based on the confidence and clarity of results across a continuum of patient care. The unique combination of molecular, cellular and tissue-based diagnostic tests provides healthcare professionals powerful information to make patient care decisions and minimize unnecessary treatment.

cobas HPV testing is clinically validated for HPV primary screening, ASC-US triage, or co-testing (HPV and Pap cytology) using the cobas 4800 or cobas 6800/8800 Systems *. The cobas HPV assays provides specific genotyping information for HPV 16 and HPV 18, the highest-risk types, while simultaneously reporting the 12 other high-risk HPV types as a pooled result, all in one test and from one patient sample. More information about cobas HPV is available at www.hpv16and18.com.

Using advanced, dual-biomarker technology to simultaneously detect p16 & Ki-67, CINtec® PLUS Cytology* definitively identifies transforming HPV infections, providing greater certainty to clinicians to stratify patients for follow-up or intervention. CINtec PLUS Cytology* is an objective triage solution for managing HPV-positive or abnormal Pap cytology primary screening results and helps address some of the limitations of traditional Pap cytology.

CINtec Histology is used to confirm the presence or absence of high-grade cervical disease in women who have had a tissue biopsy. CINtec Histology uses the p16 biomarker for a more conclusive diagnosis to provide distinctive visual confirmation of pre-cancerous cervical lesions that may be missed by H&E or morphologic interpretation alone. Both CINtec assays have been fully automated on the VENTANA BenchMark IHC/ISH instruments*.

About Human Papillomavirus and Cervical Cancer

Persistent infection with high-risk Human Papillomavirus (HPV) is the principal cause of cervical cancer in women, with HPV implicated in greater than 99 percent of cervical cancers worldwide. It can take 10 to 15 years or longer for cervical cancer to develop, so knowing a woman's individual risk and finding disease

early, before cancer develops, is an important prevention strategy. The World Health Organization estimates there are more than 500,000 new cases of cervical cancer annually.

About the cobas 6800/8800 Systems

The cobas 6800 and cobas 8800 systems are fully integrated, automated solutions that introduce a new standard for routine molecular testing in the areas of viral load monitoring, donor screening, women's health and microbiology. Based on Nobel prize-winning PCR technology, the systems are designed to deliver full automation, increased throughput and faster turnaround time, providing users with greater flexibility to increase overall workflow efficiencies.

The systems provide up to 96 results in less than 3.5 hours and a total of 384 results for the cobas 6800 System and 960 results for the cobas 8800 System in an eight-hour shift. Both make it possible for labs to perform up to three tests in the same run with no pre-sorting required. The systems also enable up to eight hours (cobas 6800) and four hours (cobas 8800) of walk-away time with minimal user interaction.

Additional molecular assays for use on the cobas 6800/8800 Systems include: cobas HIV-1, cobas HCV; cobas HBV and cobas CMV plus three next-generation assays for donor screening: cobas MPX, cobas WNV and cobas HEV.

For more information about the Systems, visit www.cobas68008800.com or <http://molecular.roche.com>.

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 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.

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. 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 for improving patient access to medical innovations by working with all relevant stakeholders. 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 eight years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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 <http://www.roche.com>.

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References

¹Walboomers JM, Jacobs MV, Manos MM, et al. Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. J Pathol. 1999; 189:12-19.