Media Release

Indianapolis, August 21, 2018

New cervical cancer screening guidelines recommend HPV testing alone

- **US Preventive Services Task Force updated guidelines add primary HPV testing as recommended screening method for women 30-65**
- **Guidelines broaden recommended screening methods available to healthcare providers and their patients to make informed choices**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today commended the United States Preventive Services Task Force (USPSTF) for issuing new cervical cancer screening guidelines that use scientific evidence as the basis for recommending, for the first time, human papillomavirus (HPV) testing alone as the first-line screening test to detect cervical cancer and precancer.

The USPSTF Recommendation Statement, published today in the Journal of the American Medical Association, assigns a grade of "A"—indicating the service is recommended and there is a "high certainty that the net benefit is substantial"—for high-risk HPV testing every five years for women 30 to 65. It also retains prior recommendations for Pap testing alone every three years for women 21 to 65 and cotesting (Pap plus HPV) for women 30-65. The task force noted that it found convincing evidence that these screening practices substantially reduce the incidence of cervical cancer and mortality.

"This action by the USPSTF to recommend HPV testing alone represents a milestone in women's health, because it shows that U.S. clinical guidelines are catching up to science and to the rest of the world," said Lee Shulman, MD, FACMG, FACOG, professor in obstetrics and gynecology and chief of the Division of Clinical Genetics at the Feinberg School of Medicine at Northwestern University. "Multiple studies have shown that you get the same benefit from HPV testing alone that you do from cotesting, but at a lower cost. This Recommendation moves the U.S. closer to common ground with all of the major countries in Europe and Australia who began implementing primary HPV screening programs some time ago."

Roche
Diagnostics Division
9115 Hague Road
Indianapolis, IN 46256
Corporate Communications
Tel 317 521 2000
usdiagnostics.roche.com

Several leading medical societies in the U.S., including the American Congress of Obstetricians and Gynecologists (ACOG), currently support the use of an HPV test approved by the FDA for first-line primary screening (i.e., without an accompanying Pap test) in women age 25 and older, in conjunction with an FDA-approved screening algorithm. When the U.S. Food and Drug Administration (FDA) approved the first HPV test for primary screening in 2014, it included in its approval a testing algorithm that directed healthcare providers to follow a specific protocol for patient management, which included a role for Pap testing and colposcopy as follow-up tests for certain types of HPV test results.

"Using HPV DNA testing as the primary screening test and utilizing the Pap test to triage women who are positive for HPV enables healthcare providers to utilize the two tests in their most appropriate roles to achieve the best cancer prevention strategy," said Alan Wright, MD, MPH, chief medical officer at Roche Diagnostics. "By using the more sensitive test—HPV—for first-line screening, caregivers can safely send home women who test negative for high-risk HPV. We're glad to see the USPSTF incorporate the latest science to help healthcare professionals provide the best care for patients and advance the effort to prevent cervical cancer."

The USPSTF Recommendation Statement, which was circulated in draft form for public comment in September 2017, replaces the 2012 Recommendation Statement.

About US Preventive Services Task Force Recommendations

Created in 1984, the U.S. Preventive Services Task Force is an independent, volunteer panel of national experts in prevention and evidence-based medicine. The Task Force works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications. Their recommendations are based on a rigorous review of existing peer-reviewed evidence and are intended to help primary care clinicians and patients decide together whether a preventive service is right for a patient's needs.

Since 1998, the Agency for Healthcare Research and Quality (AHRQ) has been authorized by the U.S. Congress to convene the Task Force and to provide ongoing scientific, administrative, and dissemination support.

About Primary HPV Testing

The U.S. Food and Drug Administration (FDA) approved the first HPV test (cobas HPV Test) for first-line primary cervical cancer screening of women 25 and older in March of 2014,

following a unanimous recommendation from the independent Microbiology Devices Panel of the FDA's Medical Devices Advisory Committee. The cobas HPV Test had been initially approved by the FDA in 2011 for use in screening women 21 and older with unclear Pap test results and for co-testing with a Pap test in women 30 and older. Currently utilized by more than 250 labs in the U.S., it is the only test approved in the U.S. for all three HPV testing options supported by major medical societies.

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. The National Cancer Institute estimates that there will be more than 13,000 new cases of cervical cancer and more than 4,000 deaths due to the disease in the United States in 2018. The World Health Organization estimates there are more than 500,000 new cases of cervical cancer annually.

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 personalized 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 to improve patient access to medical innovations by working with all relevant stakeholders. 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. Roche has been recognized as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine 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

2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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 or usdiagnostics.roche.com.

For further information, please contact:
Mike Weist
Communications Business Partner
Roche Diagnostics Corporation
(317) 371-0035 m
mike.weist@roche.com