Roche receives FDA approval for first companion diagnostic to identify endometrial cancer patients eligible for immunotherapy

- **About 90,000 women globally die from endometrial cancer each year[1]**
- **VENTANA MMR RxDx Panel is the first immunohistochemistry predictive test in endometrial cancer for treatment with the anti-PD1 immunotherapy JEMPERLI (dostarlimab-gxly)**
- **Roche/GSK collaboration represents an important step towards a personalised healthcare strategy that can help identify patients who are most likely to benefit from a specific therapy**

Basel, 23 April 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced U.S. Food and Drug Administration (FDA) approval of the VENTANA MMR RxDx Panel for advanced or recurrent endometrial cancer patients. MMR is a molecular mechanism that functions to correct certain errors that can spontaneously occur during DNA replication. Testing can identify patients eligible for treatment with JEMPERLI (dostarlimab-gxly) monotherapy, an anti-PD1 immunotherapy from GlaxoSmithKline (GSK) that was approved by the FDA on 22 April 2021.

Endometrial cancer is the most common gynecologic cancer in the U.S. and the fourth most common cancer in women in North America.[2] In addition, about 90,000 women globally die from endometrial cancer each year.[1] There are limited treatment options for women whose disease progresses on or after first-line therapy and this is the first companion diagnostic to identify endometrial cancer patients eligible for anti-PD1 immunotherapy.

“We are excited to launch this companion diagnostic test with GSK to help recurrent or advanced endometrial cancer patients with limited treatment options,” said Thomas Schinecker, CEO of Roche Diagnostics. “This test provides clinicians with an effective tool to identify patients best suited for treatment with GSK’s JEMPERLI, providing a new therapeutic option for women with MMR-deficient endometrial cancer whose disease progresses on or following initial chemotherapy treatment.”

MMR deficiency is most common in endometrial cancer. This companion diagnostic (CDx) provides clinicians with a standardised testing option that uses a comprehensive panel of DNA mismatch repair (MMR) biomarkers tested by immunohistochemistry (IHC). FDA approval of the VENTANA MMR RxDx Panel provides clinicians with access to a fully automated, easy-to-use MMR test to identify patients who are eligible for therapy with JEMPERLI.

About the VENTANA MMR RxDx Panel
The VENTANA MMR RxDx Panel is a label expansion of Roche’s current on-market VENTANA MMR IHC Panel. VENTANA MMR RxDx Panel is a qualitative immunohistochemistry test intended for use in the assessment of mismatch repair (MMR) proteins (MLH1, PMS2, MSH2 and MSH6) in formalin-fixed, paraffin-embedded (FFPE) endometrial carcinoma tissue by light microscopy. The OptiView DAB IHC Detection Kit is used for MLH1, MSH2 and MSH6, and the OptiView DAB IHC Detection Kit with the

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

OptiView Amplification Kit is used for PMS2 on a VENTANA BenchMark ULTRA instrument. DNA mismatch repair (MMR) proteins have been clinically proven to be predictive biomarkers for PD-1 targeted therapy; specifically, a loss of expression of one or more MMR proteins might predict an increased likelihood of response to such therapy.[3,4,5] PD-1 inhibitors can be effective in cancers with a high frequency of MMR deficiency and/or microsatellite-instability, high (MSI-H) including endometrial cancer.[3,5] MMR is a conserved molecular mechanism that functions to correct the improper base substitutions that spontaneously occur during DNA replication. Defects in the MMR machinery have been attributed to mutations in the MMR proteins.

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 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.

References

[1] Bray F, Ferlay J, et al, Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. (2018) 68:394–424. 10.3322/caac.21492

[2] Lortet-Tieulent J, J Ferlay, F Bray, and A Jemal. (2018) International patterns and trends in endometrial cancer incidence, 1978-2013. J Natl Cancer Inst. 110, 354-361.

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

[3] Lee YC, S Lheureux, and AM Oza. (2017) Treatment strategies for endometrial cancer: current practice and perspective. Curr Opin Obstet Gynecol. 29, 47-58.
[4] GSK website, https://www.gsk.com/en-gb/media/press-releases/data-from-garnet-study-indicates-robust-activity-of-dostarlimab-in-patients-with-advanced-or-recurrent-endometrial-cancer/
[5] Kato M, Takano M, Miyamoto M, et al. DNA mismatch repair-related protein loss as a prognostic factor in endometrial cancers. J Gynecol Oncol. 2015:26(1):40-45.

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. Daniel Grotzky
Phone: +41 61 688 31 10

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mählitz
Phone: +41 79 327 54 74

Nathalie Meetz
Phone: +41 61 687 43 05

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

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

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

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

Investor Relations North America

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

Dr. Lisa Tuomi
Phone: +1 650 467 8737
e-mail: tuomi.lisa@gene.com