Media Release

Roche launches VENTANA PD-L1 (SP142) Assay in CE markets as first companion diagnostic to identify triple-negative breast cancer patients eligible for treatment with Tecentriq

- **This launch represents an important step in Roche's personalised healthcare strategy to fit treatments to patients who can benefit most from a specific medicine**
- **Each year 300,000 patients around the world are diagnosed with triple-negative breast cancer, an aggressive disease with limited treatment options[1,2]**
- **VENTANA PD-L1 (SP142) Assay helps identify triple-negative breast cancer patients most likely to benefit from treatment with Tecentriq plus chemotherapy**

Basel, 29 August 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the expanded use of the VENTANA PD-L1 (SP142) Assay[3,4] in triple-negative breast cancer (TNBC) for patients living in CE (Conformité Européene) markets where the Roche cancer immunotherapy medicine Tecentriq® is approved. It is the first companion diagnostic to aid in identifying triple-negative breast cancer patients eligible for treatment with Tecentriq (atezolizumab)[5] plus chemotherapy (nab-paclitaxel).[6] Assessment of PD-L1 biomarker status on tumour-infiltrating immune cells with the assay is essential for identifying those patients most likely to benefit from the treatment.

Today's announcement follows the U.S. Food and Drug Administration approval of the assay in March 2019 as the first companion diagnostic to identify triple-negative breast cancer patients eligible for the Tecentriq combination. A diagnosis of triple-negative breast cancer means that the three most common proteins associated with breast cancer growth – estrogen receptor, progesterone receptor and HER2/neu – are not expressed on the tumour.

"Until recently, the only treatment option for metastatic triple-negative breast cancer patients was chemotherapy," said Thomas Schinecker, Head of Roche Diagnostics. "With our expanding menu of companion diagnostics and targeted cancer immunotherapies, Roche is proud to continue to deliver on our mission to make personalised healthcare a global reality, ensuring the right treatment for the right patient at the right time."

The VENTANA PD-L1 (SP142) Assay was developed to enhance visual contrast of tumour-infiltrating immune cell staining. In triple-negative breast cancer, PD-L1 is primarily expressed on tumour-infiltrating immune cells rather than on tumour cells themselves.[7]

Launched in 2016, the VENTANA PD-L1 (SP142) Assay is the primary diagnostic assay within the Tecentriq clinical development program and was used to enroll and stratify patients in Tecentriq clinical trials. It was the enrollment assay used in the IMpassion130 trial, the first positive phase III immunotherapy regimen study in triple-negative breast cancer. The assay was the first to evaluate patient PD-L1 biomarker status using immune cell staining and scoring within the tumour microenvironment.[8]

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

About the VENTANA PD-L1 (SP142) Assay
The VENTANA PD-L1 (SP142) Assay is available on the fully automated BenchMark IHC/ISH series instruments and uses the OptiView DAB IHC Detection Kit with OptiView Amplification Kit. The VENTANA PD-L1 (SP142) Assay performs specific staining of tumour cells and immune cells. The assay was previously approved by the FDA and CE marked for use as a companion diagnostic in urothelial carcinoma (UC)5 and as a predictive assay in non-small cell lung cancer (NSCLC) with Tecentriq. See the Tecentriq product label for more information on PD-L1 expression levels in therapeutic guidance for various cancer indications.

About the IMpassion130 study
The IMpassion130 study is a phase III, multicenter, randomized, double-blind study evaluating the efficacy, safety and pharmacokinetics of Tecentriq plus nab-paclitaxel compared with placebo plus nab-paclitaxel in people with unresectable locally advanced or metastatic triple-negative breast cancer who have not received prior systemic therapy for metastatic breast cancer (mBC). For details of the study go to www.roche.com.

About Tecentriq
Tecentriq is a monoclonal antibody designed to bind with a protein called PD-L1, which is expressed on tumour cells and tumour-infiltrating immune cells, blocking its interactions with both PD-1 and B7.1 receptors. By inhibiting PD-L1, Tecentriq may enable the activation of T cells. Tecentriq is a cancer immunotherapy that has the potential to be used as a foundational combination partner with other immunotherapies, targeted medicines and various chemotherapies across a broad range of cancers. The development of Tecentriq and its clinical programme is based on our greater understanding of how the immune system interacts with tumours and how harnessing a person's immune system combats cancer more effectively.

Tecentriq is approved in the US, EU and countries around the world, either alone or in combination with targeted therapies and/or chemotherapies in various forms of non-small cell and small cell lung cancer, certain types of metastatic urothelial cancer, and in PD-L1-positive triple-negative breast cancer.

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 tenth consecutive year, Roche has been

recognised as the most sustainable company 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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(6):394-424.
[2] Eliyatkin N, Yalcin E, et al. Molecular Classification of Breast Carcinoma: From Traditional, Old-Fashioned Way to A New Age, and A New Way. J Breast Health. 2015;11(2):59-66.
[3] This product is intended for in vitro diagnostic (IVD) use.
[4] VENTANA PD-L1 (SP142) Assay may not be available for some indications and/or cutoffs in all geographies.
[5] In Switzerland Tecentriq is approved for non-small cell lung cancer only.
[6] Abraxane® [paclitaxel protein-bound particles for injectable suspension (albumin-bound); *nab*-paclitaxel]
[7] Emens, et al. SABCS 2018 (Abstract GS1-04)
[8] The PD-L1 (SP142) Assay is proven to identify patients most likely to respond to treatment with Tecentriq, as demonstrated by higher overall response rates in Cohort 2 of the IMvigor 210 clinical trial. The novel approach uses immunohistochemistry (IHC) technology designed to visually enhance and score PD-L1 protein on tumour-infiltrating immune cells. In an analysis based on 14.4 months of median follow up, Tecentriq shrank tumours (ORR) in 15 percent (95% CI: 11, 19) of people evaluable for efficacy (n=310) whose disease progressed after platinum-based chemotherapy. Tecentriq shrank tumours in 26 percent (95% CI: 18, 36) of people whose disease had medium and high levels of PD-L1 expression (n=100).

Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com
- Nicolas Dunant (Head)
- Patrick Barth
- Ulrike Engels-Lange
- Karsten Kleine
- Barbara von Schnurbein