Media Release

Roche's Tecentriq plus platinum-based chemotherapy reduced the risk of disease worsening or death in people with previously untreated advanced bladder cancer

- **IMvigor130 is the first positive Phase III study of a cancer immunotherapy combination in previously untreated advanced bladder cancer**
- **Data will be shared with health authorities globally, including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA)**

Basel, 5 August 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMvigor130 study met its co-primary endpoint of investigator-assessed progression-free survival (PFS). The combination of Tecentriq® (atezolizumab) plus platinum-based chemotherapy showed a statistically significant reduction in the risk of disease worsening or death (PFS) in people with previously untreated locally advanced or metastatic urothelial carcinoma (mUC) compared with chemotherapy alone. Encouraging overall survival (OS) results were observed at this interim analysis; however, these data are not yet mature and follow-up will continue until the next planned analysis.

Safety in the Tecentriq plus chemotherapy arm appeared consistent with the known safety profiles of the individual medicines and no new safety signals were identified with the combination. Results will be presented at an upcoming medical meeting and shared with health authorities globally, including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA).

"IMvigor130 is the first positive Phase III study of a cancer immunotherapy combination in previously untreated advanced bladder cancer, an aggressive disease with high unmet need," said Sandra Horning, M.D., Chief Medical Officer and Head of Global Product Development. "These results support our broad clinical development programme for Tecentriq in bladder cancer, as well as our approach of combining immunotherapy with chemotherapy or other medicines to improve patient outcomes, and we look forward to discussing them with health authorities."

Tecentriq was the first cancer immunotherapy approved in bladder cancer. Currently, there are four ongoing Phase III studies evaluating Tecentriq alone and in combination with other medicines in early and advanced bladder cancer. Roche has an extensive development programme for Tecentriq, including multiple ongoing and planned Phase III studies, across lung, genitourinary, skin, breast, gastrointestinal, gynaecological, and head and neck cancers. This includes studies evaluating Tecentriq both alone and in combination with other medicines.

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About the IMvigor130 study
IMvigor130 is a multicentre, partially blinded, randomised Phase III study, evaluating the efficacy and safety of Tecentriq in combination with chemotherapy or alone versus chemotherapy alone for people with mUC who have not received prior systemic therapy for metastatic disease. It enrolled 1213 people who were randomised to receive:

- Tecentriq plus platinum-based chemotherapy (gemcitabine with either cisplatin or carboplatin), or
- Tecentriq, or
- Platinum-based chemotherapy (gemcitabine with either cisplatin or carboplatin) plus placebo (control arm).

In the Tecentriq combination arm, co-primary endpoints are OS and PFS as assessed by investigator using Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1).

About bladder cancer
In 2018, there were over half a million new cases of bladder cancer diagnosed globally, with around 200,000 deaths from the disease. [1] Urothelial carcinoma, which develops in the cells of the bladder lining, is the most common type of bladder cancer, accounting for about 90% of all cases. [2] In total, 30% of cases are considered advanced based on muscle-invasive or metastatic disease. [3]

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/or 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 mUC, and in PD-L1-positive triple-negative breast cancer.

About Roche in cancer immunotherapy
For more than 50 years, Roche has been developing medicines with the goal to redefine treatment in oncology. Today, we're investing more than ever in our effort to bring innovative treatment options that help a person's own immune system fight cancer.

By applying our seminal research in immune tumour profiling within the framework of the Roche-devised cancer immunity cycle, we are accelerating and expanding the transformative benefits with Tecentriq to a greater number of people living with cancer. Our cancer immunotherapy development programme takes a comprehensive approach in pursuing the goal of restoring cancer immunity to improve outcomes for patients.

To learn more about the Roche approach to cancer immunotherapy please follow this link: http://www.roche.com/research_and_development/what_we_are_working_on/oncology/cancer-immunotherapy.htm

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

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[3] Kaufman DS, Shipley WU, Feldman AS. Bladder cancer. Lancet. 2009;374:239-249.

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