Media Release

Roche provides an update on Phase III study of Tecentriq in people with muscle-invasive urothelial cancer

Basel, 24 January 2020 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMvigor010 study evaluating Tecentriq® (atezolizumab) as an adjuvant (after surgery) monotherapy treatment did not meet its primary endpoint of disease-free survival (DFS) compared to observation in people with muscle-invasive urothelial cancer (MIUC). Safety for Tecentriq appeared consistent with the known safety profile of the medicine, and no new safety signals were identified.

"Reducing the risk that muscle-invasive urothelial cancer will recur after surgery is very difficult, and we are disappointed that we were not able to significantly prolong disease-free survival," said Levi Garraway, M.D., Ph.D., Chief Medical Officer and Head of Global Product Development. "We remain committed to exploring the potential benefits of immunotherapy for more people with early cancers."

The goal in treating MIUC early is to reduce the risk of the disease recurring or spreading to other parts of the body. More treatment options following surgery are needed as approximately half of people with MIUC will develop a recurrence of their disease within 2 years of surgery.[1]

In addition to ongoing Phase III studies in early and advanced bladder cancer, Roche has an extensive development programme for Tecentriq, including multiple ongoing and planned Phase III studies across several types of lung, genitourinary, skin, breast, gastrointestinal, gynaecological, and head and neck cancers. This includes studies evaluating Tecentriq both alone and in combination with other medicines.

About the IMvigor010 study
IMvigor010 is a global Phase III, open-label, randomised, controlled study designed to evaluate the efficacy and safety of adjuvant treatment with Tecentriq compared to observation in 809 people with MIUC, who are at high risk for recurrence following resection. The primary endpoint is DFS as assessed by investigator, which is defined as the time from randomisation to invasive urothelial cancer recurrence or death.

About bladder cancer and muscle-invasive urothelial cancer
In 2018, there were over half a million new cases of bladder cancer diagnosed globally, with approximately 200,000 deaths from the disease.[2] Urothelial cancer is the most common type of bladder cancer, accounting for about 90–95% of all cases.[3] MIUC is a type of urothelial cancer that has spread into the muscle of the bladder, ureter or renal pelvis.[4] Approximately 25% of new cases of bladder cancer are diagnosed with muscle-invasive disease,[5] which is associated with a poorer prognosis than non-MIUC.[4]

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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 metastatic 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 eleventh 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 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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