

Roche provides update on Phase III study of Tecentriq in women with advanced stage ovarian cancer

Basel, 13 July 2020 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMagyn050 study showed that the addition of Tecentriq® (atezolizumab) to Avastin® (bevacizumab), paclitaxel and carboplatin did not meet its primary endpoint of progression-free survival (PFS) for the front-line treatment of women with newly diagnosed advanced stage ovarian cancer. Topline safety data indicate that safety for Tecentriq in combination with Avastin, paclitaxel and carboplatin was consistent with the known safety profile of the combination.

“Ovarian cancer remains one of the most aggressive cancers and is difficult to treat in its advanced stages,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “While we are disappointed by these results, we remain committed to improving outcomes for women living with this disease and are pleased that Avastin remains a key component in the treatment of front-line ovarian cancer.”

Data for the overall survival (OS) co-primary endpoint are currently immature and follow-up will continue until the next planned analysis. Results from IMagyn050 will be further evaluated in order to inform the Tecentriq gynaecologic development programme. The Tecentriq programme in ovarian cancer and cervical cancers builds on the combination with Avastin, which has helped women with newly diagnosed, advanced or relapsed ovarian and cervical cancers live without their disease getting worse, as demonstrated in results across seven pivotal Phase III trials that involved more than 5,000 women.

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.

About the IMagyn050 study

IMagyn050 is a Phase III, multicentre, randomised, double-blind study evaluating the efficacy and safety of Tecentriq in combination with Avastin, paclitaxel and carboplatin compared with placebo plus Avastin, paclitaxel and carboplatin in women with Stage III or IV ovarian cancer who are undergoing neoadjuvant or adjuvant therapy. Patients were randomised 1:1 either before or after tumour reductive surgery. The co-primary endpoints are investigator-determined PFS and OS, both in the intent-to-treat (ITT) population and PD-L1-positive subpopulation. Key secondary endpoints include objective response rate, safety and tolerability, as well as patient-reported improvement in abdominal pain and bloating.

The IMagyn050 study is being conducted in collaboration with The GOG Foundation, Inc. (GOG Foundation) [GOG-3015] and the European Network of Gynaecological Oncological Trial groups (ENGOT) [ENGOT OV-39].

About ovarian cancer

Ovarian cancer is the 8th most commonly occurring cancer in women worldwide, with nearly 300,000 new cases diagnosed each year.^{1,2} Ovarian cancer remains the leading cause of death from any gynaecologic malignancy, due to the fact that the majority of patients are not diagnosed until they present with already advanced stage disease, resulting in a 5-year survival rate of less than 30%.^{3,4}

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. In the US, Tecentriq in combination with Avastin is approved for people with unresectable or metastatic hepatocellular carcinoma.

About Avastin

Avastin is a prescription-only medicine that is a solution for intravenous infusion. It is a biologic antibody designed to specifically bind to a protein called VEGF that plays an important role throughout the lifecycle of the tumour to develop and maintain blood vessels, a process known as angiogenesis. Avastin is designed to interfere with the tumour blood supply by directly binding to the VEGF protein to prevent interactions with receptors on blood vessel cells. The tumour blood supply is thought to be critical to a tumour's ability to grow and spread in the body (metastasise).

About Roche in cancer immunotherapy

Roche's rigorous pursuit of groundbreaking science has contributed to major therapeutic and diagnostic advances in oncology over the last 50 years, and today, realising the full potential of cancer immunotherapy is a major area of focus. With over 20 molecules in development, Roche is investigating the potential benefits of immunotherapy alone, and in combination with chemotherapy, targeted therapies or other immunotherapies with the goal of providing each person with a treatment tailored to harness their own unique immune system to attack their cancer. Our scientific expertise, coupled with innovative pipeline and extensive partnerships, gives us the confidence to continue pursuing the vision of finding a cure for cancer by ensuring the right treatment for the right patient at the right time.

In addition to Roche's approved PD-L1 checkpoint inhibitor, Tecentriq® (atezolizumab), Roche's broad cancer immunotherapy pipeline includes other checkpoint inhibitors, such as tiragolumab, a novel cancer immunotherapy designed to bind to TIGIT, individualised neoantigen therapies and T-cell bispecific

antibodies. To learn more about Roche's scientific-led 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 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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.

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References

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[4] Cancer.Net. Ovarian, Fallopian Tube, and Peritoneal Cancer: Statistics. [Internet; cited 20 April 2020] Available from: <https://www.cancer.net/cancer-types/ovarian-fallopian-tube-and-peritoneal-cancer/statistics>.

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