Media & Investor Release

Roche's Tecentriq showed significant overall and disease-free survival benefits in bladder cancer with ctDNA-guided treatment

- **Tecentriq reduced the risk of death by 41% and the risk of disease recurrence or death by 36% compared with placebo[1]**
- **IMvigor011 is the first global phase III study to read out pioneering a ctDNA-guided approach to post-surgery treatment in muscle-invasive bladder cancer**
- **Data being presented as part of the Presidential Symposium at the ESMO Congress 2025**

Basel, 20 October 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today positive results from the phase III IMvigor011 study evaluating Tecentriq® (atezolizumab) as an adjuvant treatment for people with muscle-invasive bladder cancer (MIBC) who are at risk of recurrence after surgery (cystectomy) and have detectable circulating tumour DNA (ctDNA). In this ctDNA-guided setting, Tecentriq reduced the risk of death (overall survival, OS) by 41% and the risk of disease recurrence or death (disease-free survival, DFS) by 36%, both compared with placebo. This ctDNA-guided approach, using Natera's Signatera™ ctDNA Molecular Residual Disease (MRD) test, spared people at low risk of recurrence from unnecessary treatment and side effects. The safety profile was consistent with previous studies of Tecentriq.[1]

These results are being presented as part of the Presidential Symposium at the European Society for Medical Oncology (ESMO) Congress 2025. They will also be discussed with health authorities, including the U.S. Food and Drug Administration (FDA).

"These clinically meaningful results show that Tecentriq helped people with muscle-invasive bladder cancer live longer and without their disease returning," said Levi Garraway, Roche's Chief Medical Officer and Head of Global Product Development. "The use of serial ctDNA testing to detect molecular residual disease may also advance bladder cancer treatment by combining a precision diagnostic with cancer immunotherapy."

"Even after surgery, most people with muscle-invasive bladder cancer will face the physical and emotional toll of further treatment," said Professor Thomas Powles, lead principal investigator of IMvigor011, Professor of Genitourinary Oncology; Chair of Barts Cancer Centre at St. Bartholomew's Hospital. "These results indicate that with Signatera ctDNA testing, we may be able to identify those at risk of recurrence who could benefit from adjuvant atezolizumab treatment and spare others from unnecessary therapy, paving the way for a more personalised treatment approach."

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

At median follow up of 16.1 months, median DFS was 9.9 months in the Tecentriq arm versus 4.8 months in the placebo arm (stratified hazard ratio [HR]=0.64; 95% CI: 0.47-0.87, p =0.0047). Median OS was 32.8 months in the Tecentriq arm versus 21.1 months in the placebo arm (HR=0.59; 95% CI: 0.39-0.90, p=0.0131). People who persistently tested for no detectable ctDNA had low risk of recurrence.[1]

More than 150,000 people worldwide are diagnosed with MIBC each year.[2,3] It is an aggressive type of cancer, with poor long-term outcomes and high treatment burden.[4] Despite this, personalised treatment approaches lag behind other cancer types.[5] ctDNA-guided treatment could change this, by helping healthcare professionals tailor treatment more precisely to improve clinical benefit and reduce unnecessary intervention.[1]

About the IMvigor011 study

IMvigor011 [NCT04660344] is a global phase III, randomised, placebo-controlled, double-blind study designed to evaluate the efficacy and safety of adjuvant treatment with Tecentriq® (atezolizumab) compared with placebo in participants with muscle-invasive bladder cancer (MIBC) who are circulating tumour DNA (ctDNA)-positive and are at risk of recurrence following cystectomy. IMvigor011 utilised Natera's Signatera™ as the clinical trial assay. This personalised ctDNA test for the detection of MRD is currently under review by the FDA for use as a companion diagnostic. 761 people participated in the surveillance phase of IMvigor011 and those with positive Signatera tests (250 people) joined the treatment phase, where they received either Tecentriq or placebo. The primary endpoint is investigator-assessed disease-free survival (DFS). Secondary endpoints include overall survival (OS) and tolerability, amongst others.

About Tecentriq® (atezolizumab)

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 re-activation of T cells. Tecentriq may also affect normal cells.

Tecentriq has been approved for some of the most aggressive and difficult-to-treat forms of cancer and is the first PD-(L)1 cancer immunotherapy available in both subcutaneous and intravenous formulations. Tecentriq was the first cancer immunotherapy approved for the treatment of a certain type of early-stage (adjuvant) non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC) and hepatocellular carcinoma (HCC). Tecentriq is also approved in countries around the world, either alone or in combination with targeted therapies and/or chemotherapies, for various forms of metastatic NSCLC, certain types of metastatic urothelial cancer (mUC), PD-L1-positive metastatic triple-negative breast cancer (TNBC), BRAF V600 mutation-positive advanced melanoma and alveolar soft part sarcoma (ASPS).

About Roche in cancer immunotherapy

To learn more about Roche's scientific-led approach to cancer immunotherapy, please follow this link: https://www.roche.com/solutions/focus-areas/oncology/cancer-immunotherapy

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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

Roche Global Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 79 407 72 58

Nathalie Altermatt
Phone: +41 79 771 05 25

Simon Goldsborough
Phone: +44 797 32 72 915

Kirti Pandey
Phone: +49 172 6367262

Dr. Rebekka Schnell
Phone: +41 79 205 27 03

Sileia Urech
Phone: +41 79 935 81 48

Lorena Corfas
Phone: +34 620 29 25 51

Karsten Kleine
Phone: +41 79 461 86 83

Yvette Petillon
Phone: +41 79 961 92 50

Roche Investor Relations

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. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Investor Relations North America

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