FDA approves Roche’s Tecentriq in combination with a fluoropyrimidine and oxaliplatin for the adjuvant treatment of a certain type of stage III colon cancer

Datum	9.10.2026
Subjekt	F. Hoffmann-La Roche AG
Kontakt	<table><tr><td>Tristan Schmitz Phone: +41 79 529 70 35</td><td>Lorena Corfas Phone: +41 79 568 24 95 </td></tr><tr><td>Simon Goldsborough Phone: +44 797 32 72 915</td><td>Karsten Kleine Phone: +41 79 461 86 83 </td></tr><tr><td>Kirti Pandey Phone: +41 79 398 38 53</td><td>Yvette Petillon Phone: +41 79 961 92 50 </td></tr><tr><td>Irène Stephan Phone: +41 79 377 83 75</td><td>Albert Thottiyil Phone: +41 79 775 66 12</td></tr></table> <table><tr><td>Dr Bruno Eschli Phone: +41 61 68-75284 e-mail: bruno.eschli@roche.com</td><td>Dr Sabine Borngräber Phone: +41 61 68-88027 e-mail: sabine.borngraeber@roche.com</td></tr><tr><td> Dr Birgit Masjost Phone: +41 61 68-84814 e-mail: birgit.masjost@roche.com</td><td> </td></tr></table> <table><tr><td>Loren Kalm Phone: +1 650 225 3217 e-mail: kalm.loren@gene.com</td><td> </td></tr></table>
Region	Švýcarsko
Kategorie	Farmaceutický průmysl, Zdravotnictví a nemocnice, Věda a výzkum

FDA approval is based on results from the landmark phase III ATOMIC study, published in The New England Journal of Medicine, which showed Tecentriq plus chemotherapy reduced the risk of disease recurrence or death by 50% compared to chemotherapy alone1.

- **First approved adjuvant immunotherapy regimen for stage III dMMR colon cancer, positioning Tecentriq as a new post-surgery standard of care**
- **Nearly 25% of all colon cancers are diagnosed at stage III, and almost one in three patients with stage III colon cancer experience a recurrence within five years[2,3]**
- **Approval marks the twelfth indication for Tecentriq in the US**

Basel, 9 October 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has approved Tecentriq® (atezolizumab) and Tecentriq Hybreza® (atezolizumab and hyaluronidase-tqjs) in combination with a fluoropyrimidine and oxaliplatin for the adjuvant treatment of stage III deficient DNA mismatch repair (dMMR) colon cancer, a type of tumour characterised by high mutation rates. This approval marks the twelfth indication for Tecentriq in the US.

“This approval provides a new adjuvant treatment option for people with stage III dMMR colon cancer who face a high risk of disease recurrence,” said Levi Garraway, MD, PhD, Roche’s Chief Medical Officer and Head of Global Product Development. “Tecentriq combined with chemotherapy has the potential to become the new standard of care as the first approved immunotherapy-based regimen for this setting.”

“Until now, the adjuvant standard of care for stage III colon cancer has not differed based on mismatch repair status,” said Frank A. Sinicrope, MD, Professor of Oncology at the Mayo Clinic and US Principal Investigator for the Alliance ATOMIC trial. “This milestone represents an important therapeutic advance that leverages immunotherapy to target the specific biology of dMMR stage III

colon cancer after surgical resection. By reducing the risk of disease recurrence or death by 50%, atezolizumab plus chemotherapy is a practice-changing regimen that can improve clinical outcomes of this group of patients living with colon cancer, one of the most common cancers and a leading cause of cancer-related death."

The FDA approval is based on the landmark phase III ATOMIC study, recently published in *The New England Journal of Medicine*. ATOMIC demonstrated that adding Tecentriq to modified (m)FOLFOX6 chemotherapy reduced the risk of disease recurrence or death by 50%, compared to chemotherapy alone for people with stage III dMMR colon cancer, as determined by an immunohistochemistry test, such as the VENTANA® MMR RxDx Panel.[1] The 36-month disease-free survival was 86% for Tecentriq combined with mFOLFOX6 compared with 76% in the mFOLFOX6 alone group. The safety profile was consistent with previous studies of Tecentriq and mFOLFOX6.[1]

Colon cancer remains one of the world's most common and deadliest tumours.[4] Over one million people are diagnosed globally each year, and nearly 25% of all colon cancers are diagnosed at stage III.[2-4] Despite surgery and chemotherapy, nearly 30% of stage III patients experience disease recurrence within five years.[2,3] Approximately 15% of colon cancer patients present with dMMR or microsatellite instability-high (MSI-H) tumours, which indicate a higher mutation rate and thus have the potential to respond to immunotherapy.[5]

Roche is pursuing further regulatory filings for Tecentriq, including with the European Medicines Agency, to bring this immunotherapy-based adjuvant option to patients with dMMR colon cancer worldwide as soon as possible.

About the ATOMIC study
ATOMIC (A021502, NCT02912559) is a phase III, randomised, open-label, multicentre study investigating the addition of Tecentriq® (atezolizumab) to modified (m)FOLFOX6 chemotherapy (a combination of folinic acid, fluorouracil, and oxaliplatin) in patients with stage III colon cancer who have a deficiency in DNA mismatch repair (dMMR). The trial enrolled 712 patients. Participants were randomised 1:1 to receive either mFOLFOX6 plus Tecentriq for 12 cycles (six months) followed by Tecentriq monotherapy for 13 cycles (an additional six months), or mFOLFOX6 alone for 12 cycles. The primary endpoint is disease-free survival (DFS).

The global study in the US was sponsored by the US National Cancer Institute (NCI), part of the National Institutes of Health, and led by the Alliance for Clinical Trials in Oncology (Alliance) with participation from other NCI-funded National Clinical Trials Network (NCTN) groups. Genentech, a member of the Roche Group, provided support for the study through a Cooperative Research and Development Agreement between NCI and Genentech. The trial was led globally by Frank A. Sinicrope, MD, Professor of Oncology at the Mayo Clinic and US Principal Investigator within the Alliance. German participation in this major international academic collaboration was enabled through close cooperation between the Alliance and the AIO-Studien-gGmbH, in partnership with the AIO (Arbeitsgemeinschaft Internistische Onkologie) of the German Cancer Society (Deutsche Krebsgesellschaft, DKG), under the national leadership of Prof. Dr. Anke Reinacher-Schick (Ruhr-Universität Bochum). AIO-affiliated study sites enrolled patients during the later recruitment phase, ensuring access for eligible patients in Germany.

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.

About Roche in oncology
For over 60 years, Roche has delivered transformative medicines and diagnostics, redefining the treatment of some of the most challenging cancers. Driven by a vision of a future where cancer can be cured, we focus our efforts on cancers with the highest societal impact and where we bring deep expertise, including breast, lung, and blood cancers, while pursuing breakthrough innovation in other areas of unmet need. Our pipeline features a diverse array of modalities, from small molecules and antibodies to next-generation ADCs and allogeneic CAR T-cell therapies. By advancing best-in-class precision medicine, pioneering novel combinations, and leveraging key technologies and partnerships, Roche tackles oncology's toughest challenges with the goal of delivering life-changing outcomes for people with cancer.

About Roche
Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

For more information, please visit www.roche.com.

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Roche Global Media Relations
Phone: +41 61 688 88 88 / e-mail: media.relations@roche.com

Tristan Schmitz
Phone: +41 79 529 70 35

Lorena Corfas
Phone: +41 79 568 24 95

Simon Goldsborough
Phone: +44 797 32 72 915

Karsten Kleine
Phone: +41 79 461 86 83

Kirti Pandey
Phone: +41 79 398 38 53

Yvette Petillon
Phone: +41 79 961 92 50

Irène Stephan
Phone: +41 79 377 83 75

Albert Thottiyil
Phone: +41 79 775 66 12

Roche Investor Relations

Dr Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

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

Dr Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Investor Relations North America

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

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