

FDA grants Priority Review for Roche's Tecentriq for a certain type of stage III colon cancer

- **Filing acceptance is based on the phase III Alliance ATOMIC study showing Tecentriq plus chemotherapy reduced recurrence or death risk by 50% versus chemotherapy alone¹**
- **Nearly one in three patients with stage III colon cancer relapse within five years, highlighting a critical need for new adjuvant treatment options^{2,3}**
- **If approved, Tecentriq plus chemotherapy could provide a new standard of care for the treatment of stage III dMMR/MSI-H* colon cancer after surgery**

Basel, 11 June 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) filing for adjuvant Tecentriq® (atezolizumab) and Tecentriq Hybreza® (atezolizumab and hyaluronidase-tqjs) in combination with chemotherapy in stage III deficient DNA mismatch repair (dMMR) or microsatellite instability-high (MSI-H) colon cancer, a type of tumour characterised by high mutation rates. The FDA has granted Priority Review and is expected to make a decision on the approval by 9 October 2026.

"This filing acceptance brings us closer to establishing adjuvant Tecentriq plus chemotherapy as a new standard of care for certain types of early colon cancer," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "The ATOMIC results demonstrate that Tecentriq plus chemotherapy can substantially reduce the risk of disease recurrence or death, helping more patients remain cancer-free following surgery."

"One in three patients with stage III colon cancer will relapse within five years, underscoring the need for new adjuvant treatment options," said Michael Sapienza, CEO, Colorectal Cancer Alliance. "This milestone represents a critical step toward a reality where treatment is tailored to a patient's specific tumor biology from the very beginning, giving them a better chance of preventing a recurrence."

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

Colon cancer remains one of the world's most common and deadliest tumours.⁴ Over one million people are diagnosed globally each year, and despite surgery and chemotherapy, approximately 30% of stage III patients relapse within five years.²⁻⁴ Approximately 15% of colon cancer patients present with dMMR/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 first immunotherapy-based adjuvant option to patients with dMMR/MSI-H colon cancer worldwide.

The ATOMIC study was sponsored by the National Cancer Institute (NCI) and conducted by the Alliance for Clinical Trials in Oncology in partnership with Roche and the Arbeitsgemeinschaft Internistische Onkologie (AIO) group in Germany. It highlights Roche's commitment to working alongside leading academic groups to tackle some of the most challenging cancers.

About the ATOMIC study

ATOMIC (A021502, [NCT02912559](https://clinicaltrials.gov/ct2/show/study/NCT02912559)) is a phase III, randomised, open-label, multicentre study investigating the addition of Tecentriq® (atezolizumab) to 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 FOLFOX6 plus Tecentriq for 12 cycles (six months) followed by Tecentriq monotherapy for 13 cycles (an additional six months), or FOLFOX6 alone for 12 cycles. The primary endpoint is disease-free survival (DFS).

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 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

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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[*] Deficient DNA mismatch repair (dMMR) and microsatellite instability-high (MSI-H)

References

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