ForPatients
by Roche

Rectal CancerRectal Neoplasms

A Study of Atezolizumab With or Without Tiragolumab Following Neoadjuvant Chemotherapy in Participants With Locally Advanced Rectal Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Country	NCT05009069 ML43050

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II, Randomized, Open Label, Parallel-group Study of Atezolizumab With or Without Tiragolumab Following Neoadjuvant Chemoradiotherapy in Patients With Locally Advanced Rectal Cancer

Trial Summary:

This study will evaluate the efficacy and safety of atezolizumab plus tiragolumab or atezolizumab alone following neoadjuvant chemoradiotherapy (nCRT) in participants with locally advanced rectal cancer (LARC). The study consists of a safety run-in phase and a randomization phase. Participants enrolled in the safety run-in phase will receive atezolizumab + tiragolumab following nCRT. Upon determination of the safety of the treatment regimen, the study will be proceed to the randomization phase. Participants will be randomized in a 1:1 ratio to the atezolizumab + tiragolumab arm or atezolizumab arm.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT05009069 ML43050
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically or cytologically confirmed diagnosis of adenocarcinoma of the rectum

- Resectable locally advanced rectal cancer, with clinical stage as cT3N+M0 or cT4NanyM0 per American Joint Committee on Cancer (AJCC)/ International Union Against Cancer (UICC) 8th edition
- The inferior margin of the tumor #10cm from the anal verge
- No prior anti-cancer treatment for rectal cancer
- Availability of a representative tumor specimen that is suitable for pathological evaluation and biomarker expression analysis
- Eastern Cooperative Oncology Group (ECOG) Performance status (PS) of 0 or 1
- At least one measurable lesion per Response Evaluation Criteria in Solid Tumors (RESIST) v1.1
- Adequate hematologic and end-organ function
- For patients receiving therapeutic anticoagulation: stable anticoagulant regimen
- Negative HIV test at screening
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception, and agreement to refrain from donating eggs for at least 5 months after the final dose of atezolizumab and for 90 days after the final dose of tiragolumab, for 6 months after the final dose of capecitabine, for 6 months after the final dose of 5-FU
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods and agreement to refrain from donating sperm for at least 90 days after the final dose of tiragolumab, 3 months after final dose of capecitabine, for 6 months after the final dose of 5-FU.

Exclusion Criteria:

- Evidence of metastatic disease
- Histology consistent with small cell carcinoma, squamous carcinoma, or mixed carcinoma
- Presence of synchronous colorectal cancer
- Presence of obstruction or imminent obstruction
- Clinical symptoms or radiological suspicion of bowel perforation
- Not eligible for long-course radiotherapy
- History of malignancies other than rectal cancer within 3 years prior to screening with the exception of those with a negligible risk of metastasis or death
- Active or history of autoimmune disease or immune deficiency
- Significant cardiovascular disease
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Severe chronic or active infection within 4 weeks prior to initiation of study treatment
- Treatment with therapeutic oral or IV antibiotics within 2 weeks prior to initiation of study treatment
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures
- Uncontrolled or symptomatic hypercalcemia
- Uncontrolled diabetes or Grade # 2 abnormalities in potassium, sodium, despite standard medical management within 14 days prior to initiation of study treatment
- Prior treatment with CD137 agonists, T-cell co-stimulating, or immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, anti-PD-L1 and anti-TIGIT therapeutic antibodies
- Treatment with systemic immunostimulatory agents
- Treatment with systemic immunosuppressive medication
- Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment
- Major surgical procedure or significant traumatic injury within 28 days prior to initiation of study treatment, or abdominal surgery, abdominal interventions or significant abdominal traumatic injury within 60 days prior to initiation of study treatment
- Any other disease, medical condition or abnormality, metabolic dysfunction, alcohol or drug abuse or dependence, physical examination finding, clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the participant at high risk from treatment complications

- Treatment with any other investigational agent with therapeutic intent within 28 days prior to study treatment initiation
- History of severe allergic anaphylactic reactions to chimeric or humanized antibodies or fusion proteins
- History of allergic reactions to chemotherapy drugs (5-FU and capecitabine)
- Known dihydropyrimidine dehydrogenase (DPD) deficiency or history of severe and unexpected reactions to fluoropyrimidine therapy in participants selected to receive capecitabine
- Pregnant or breastfeeding