ForPatients
by Roche

Thymic Carcinoma

A Study to Investigate the Efficacy and Safety of Atezolizumab (Tecentriq) in Previously-Treated Patients With Advanced Thymic Carcinoma

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04321330 ML41253

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:

An Open-Label, Single Arm, Multicenter Study to Investigate the Efficacy and Safety of Atezolizumab (Tecentriq) in Previously-Treated Patients With Advanced Thymic Carcinoma

Trial Summary:

This is a phase II, open-label, single-arm, multicenter study of the efficacy and safety of atezolizumab treatment in participants with advanced thymic carcinoma who failed prior systemic therapy.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT04321330 ML41253
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histological confirmation of thymic carcinoma by the central pathology laboratory
- Advanced disease not amenable to curative treatment
- At least 1 prior line of chemotherapy
- Progression of disease must be documented prior to study entry
- Measurable disease, as defined by Response Evaluation Criteria for Solid Tumors, Version 1.1 (RECIST v1.1)

- Availability of a representative tumor specimen that is suitable for biomarkers research via central testing
- ECOG performance status 0 or1
- Life expectancy > 3 months
- Adequate hematologic and end-organ function within 14 days prior to the first study treatment
- For patients receiving therapeutic anticoagulation: stable anticoagulant regimen
- For women of childbearing potential: agreement to remain abstinent or use contraception

Exclusion Criteria:

- Disease which is amenable to radical treatment with surgery or radiation or a combination of treatments.
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- History of leptomeningeal disease
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures
- Uncontrolled or symptomatic hypercalcemia
- Active or history of autoimmune disease or immune deficiency
- 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
- Active tuberculosis
- Significant cardiovascular disease within 3 months prior to initiation of study treatment unstable arrhythmia, or unstable angina.
- Prior treatment with chemotherapy, targeted small molecule therapy, or radiation therapy within 2 weeks prior to study Day 1 or who has not recovered from adverse events due to a previously administered agent.
- Additional malignancy that is progressing or requires active treatment. Exceptions include basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or in situ cervical cancer that has undergone potentially curative therapy.