ForPatients
by Roche

Metastatic Solid Malignancy

A Study Evaluating Targeted Therapies in Participants Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04632992 ML42439

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:

MyTACTIC: An Open-Label Phase II Study Evaluating Targeted Therapies in Patients Who Have Advanced Solid Tumors With Genomic Alterations or Protein Expression Patterns Predictive of Response

Trial Summary:

This is a Phase II, multicenter, non-randomized, open-label, multi-arm study designed to evaluate the safety and efficacy of targeted therapies as single agents or in rational, specified combinations in participants with advanced unresectable or metastatic solid tumors determined to harbor specific biomarkers. Patients will be enrolled based on local testing performed at a Clinical Laboratory Improvement Amendments (CLIA)-certified or equivalently accredited diagnostic laboratory. The multi-arm structure of the MyTACTIC study allows patients with solid tumors to be treated with a drug or drug regimen tailored to their biomarker identified at screening.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT04632992 ML42439
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically or cytologically confirmed diagnosis of advanced unresectable or metastatic solid malignancy
- Positive biomarker results from a Clinical Laboratory Improvement Amendments (CLIA)-certified or equivalently accredited diagnostic laboratory and availability of a full report of the testing results. This may be from a tissue or blood sample.
- Evaluable or measurable disease
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2
- Life expectancy #8 weeks
- Adequate hematologic and end-organ function, as defined in the protocol, obtained within 14 days prior to initiation of study treatment
- Agrees to take measures to prevent pregnancy in the patient or partner
- In addition to the general inclusion criteria above, there are treatment-specific inclusion criteria that apply for each respective treatment arm (as detailed in the protocol)

Exclusion Criteria:

- Current participation or enrollment in another therapeutic clinical trial
- Symptomatic or actively progressing CNS metastases (asymptomatic patients with treated or untreated CNS metastases may be eligible, provided all protocol-defined criteria are met)
- History of leptomeningeal disease, unless noted otherwise for a specific treatment arm of the study
- Wide field radiotherapy within 14 days prior to start of study treatment
- Stereotactic radiosurgery within 7 days prior to start of study treatment
- Severe infection within 4 weeks prior to initiation of study treatment, including, but not limited to, hospitalization for complications of infections, or any active infection that, in the opinion of the investigator, could impact patient safety
- Receipt of any anticancer drug/biologic or investigational treatment 21 days prior to Cycle 1, Day 1 except hormone therapy, which can be given up to 7 days prior to Cycle 1, Day 1 (androgen blockage may be continued for male patients with prostate cancer)
- Known human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) infection with status outside of study-allowed criteria
- History of or concurrent serious medical condition or abnormality in clinical laboratory tests that precludes the patient's safe participation in and completion of the study or confounds the ability to interpret data from the study
- History of malignancy other than disease under study within 3 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Incomplete recovery from any surgery prior to the start of study treatment that would interfere with the determination of safety or efficacy of study treatment
- Major surgical procedure, other than for diagnosis, or significant traumatic injury within 4 weeks prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study
- Significant cardiovascular disease, such as New York Heart Association cardiac disease (Class II or higher), myocardial infarction, or cerebrovascular accident within 3 months prior to enrollment, unstable arrhythmias, or unstable angina
- Pregnant or breastfeeding, or intending to become pregnant during the study
- In addition to the general exclusion criteria above, there are treatment-specific exclusion criteria that apply for each respective treatment arm (as detailed in the protocol)