A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-022, an anti-TIM-3 Monoclonal Antibody, in Patients with Advanced Solid Tumors (AMBER) COHORT D: NSCLC

OVERVIEW

Study type: Interventional
Study phase: 1b
Condition: NSCLC
Intervention:
  • TSR-022
  • TSR-042
Study IDs:
  • Clinicaltrials.gov identifier: NCT02817633
  • Sponsor protocol number: 4020-01-001
Clinicaltrials.gov link: https://clinicaltrials.gov/ct2/show/study/NCT02817633
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Study PI: Christopher Croot, MD
Status: Open to accrual

ABOUT THIS STUDY

This is a multicenter, open-label, Phase 1B study evaluating the anti-TIM-3 antibody TSR-022 in combination with an anti-PD-1 antibody, in patients with advanced solid tumors. The study will be conducted in 2 parts: dose escalation and cohort expansion.

PARTICIPATION ELIGIBILITY

Participant eligibility includes age, gender, type and stage of disease, and previous treatments or health concerns. Eligibility requirements differ from study to study, and identify who can or cannot participate. If you need assistance understanding the eligibility criteria, please contact the study team.

PRE-REGISTRATION ELIGIBILITY CRITERIA:

1. Male or female at least 18 years of age
2. Histologically proven advanced (un-resectable) or metastatic NSCLC who have received ≤ 2 prior lines of treatment and have progressed following treatment with an anti-PD-(1)-1 antibody and platinum chemotherapy with positive TIM-3 expression.
3. Must consent to have fresh tumor tissue biopsy prior to dosing.
4. Females of childbearing potential must have a negative serum or urine pregnancy test and agree to use a highly effective method of contraception.
5. ECOG 0 or 1.
6. Adequate hematologic and organ function.

EXCLUSION CRITERIA

1. Radiologic or clinical progression ≤8 weeks after initiation of prior anti-PD-1 or anti-PD-L1 antibody.
2. Patients with known EGFR mutation, ALK translocation, or ROS1 mutation
3. Known uncontrolled central nervous system metastases.
4. History of HIV, pneumonitis, active Hepatitis B or C
5. Autoimmune disease requiring systemic treatment
6. Received vaccine within 7 days of first dose
7. Patients with radiologic or clinical progression ≤ 8 weeks after initiation of a prior anti-PD-1 or anti-PD-L1 antibody