NCT04982224 | PHASE 1/2 ENROLLING

Study of investigational REGN5093-M114 in patients with advanced **non small-cell lung cell cancer**

Primary Objective: evaluate the safety, tolerability, and pharmacokinetics of a METxMET bispecific antibody-drug conjugate in patients with MET-overexpressing NSCLC

PATIENTS WITH ADVANCED NSCLC (N≈83)

OPEN LABEL INTERVENTION

Phase 1

Dose escalation: REGN5093-M114 (IV)

Phase 2

Dose expansion: REGN5093-M114 (IV)

Primary Endpoints

Phase 1: Safety and tolerability
Phase 1: Pharmacokinetics
Phase 2: Objective response rate

Secondary Endpoints

Phase 1: Objective response rate
Duration of response
Disease control rate
Time to response
Progression-free survival
Overall survival
Phase 2: Safety and tolerability
Phase 2: Pharmacokinetics

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT04982224

This information is intended for investigators interested in open clinical trials.
REGN5093-M114 is an investigational agent and has not been evaluated by any regulatory authority.

IV, intravenous; N, number of patients; NSCLC, non-small cell lung cancer; MET, mesenchymal epithelial transition.

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REGN5093-M114

An Investigational METxMET Bispecific Antibody-Drug Conjugate

Designed to target two distinct epitopes on the MET receptor to deliver a cytotoxic drug to MET-overexpressing tumor cells[1]

SELECTED INCLUSION CRITERIA[a]

- Histologically confirmed NSCLC that is advanced and for which there are no approved therapies available
- Newly obtained biopsy tissue availability
- **Expansion only:** At least one lesion that is measurable by RECIST v1.1
- MET overexpression by central IHC analysis
- 0 or 1 — ECOG PS 0 or 1
- Adequate organ and bone marrow function

SELECTED EXCLUSION CRITERIA[a]

- Prior treatment with an approved or investigational systemic therapy or investigational device within 14 days of first study drug administration
- Unresolved previous acute toxicity from prior therapy
- Received radiation therapy or major surgery within 14 days of first administration of study drug
- Secondary malignancy that is progressing or requires active treatment
- Untreated or active primary brain tumor, CNS metastases, leptomeningeal disease, or spinal cord compression
- Uncontrolled infection with HIV, hepatitis B, or hepatitis C infection
- Encephalitis, meningitis, organic brain disease (e.g. Parkinson's disease) or uncontrolled seizures in the year prior to first dose of study therapy

For more information, visit www.clinicaltrials.gov or please call [+353 (0)61 533 400 or 844 REGN-MID].
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[a]Inclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on clinicaltrials.gov for complete details.

CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; HIV, human immunodeficiency virus; IHC, immunohistochemistry; MET, mesenchymal epithelial transition; NSCLC, non small-cell lung cancer; RECIST, Response Evaluation Criteria in Solid Tumors.

Current per clinicaltrials.gov as of November 29, 2023.

1. Regeneron Investor Event ESMO 2021. Available at: https://investor.regeneron.com/static-files/95baba22-304d-484f-a02c-a95f3043f58c. Accessed July 13, 2023.

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