

NCT04982224

PHASE 1/2 ENROLLING

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

# 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<sup>1</sup>

### SELECTED INCLUSION CRITERIA<sup>a</sup>



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



ECOG PS 0 or 1



Adequate organ and bone marrow function

### SELECTED EXCLUSION CRITERIA<sup>a</sup>



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](https://www.clinicaltrials.gov) or please call 844 REGN-MID.  
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<sup>a</sup>Inclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on [clinicaltrials.gov](https://www.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](https://www.clinicaltrials.gov) as of September 14, 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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