COMBINE-EGFR-1 (NCT04626635) | PHASE 1/2 ENROLLING

Study of investigational REGN7075 + cemiplimab in patients with **advanced solid tumors**

Primary Objective: evaluate the safety, tolerability, and antitumor activity of REGN7075 + cemiplimab in adult patients with advanced solid tumors

PATIENTS WITH ADVANCED SOLID TUMORS (N≈769)

OPEN LABEL INTERVENTION

Dose Escalation

- **REGN7075 monotherapy** (IV or SC) **QW**
- **REGN7075 + cemiplimab** (IV or SC) **QW or Q3W**

Dose Expansion Cohorts

REGN7075 (IV or SC) QW or Q3W + Cemiplimab (IV or SC) Q3W

A	B	C	D	E	F	G	H
TNBC	**CSCC**	**NSCLC**	**HNSCC**	**MSS-CRC** With active liver metastases and/or active peritoneal metastases	**MSS-CRC** With isolated lung/lymph node metastases	**EGFR-mutant NSCLC** Post 3rd generation TRKI	**EGFR-mutant NSCLC** Post 3rd generation TKI and post platinum-doublet chemotherapy

Primary Endpoints

Safety and tolerability
Objective response rate

Key Secondary Endpoints

- Pharmacokinetics
- Overall survival
- Progression-free survival
- Duration of response
- Complete response
- Disease control rate
- Immunogenicity

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT04626635

This information is intended for investigators interested in open clinical trials.
The use of REGN7075 + cemiplimab described herein is investigational and has not been evaluated by any regulatory authority.
Please see full prescribing information in your country for cemiplimab.

CSCC, cutaneous squamous cell carcinoma; EGFR, epidermal growth factor; HNSCC, head and neck squamous cell carcinoma; IT, intratumoral; IV, intravenous; MSS-CRC, microsatellite-stable colorectal cancer; N, number of patients; NSCLC, non-small cell lung cancer; Q1W, administered every week; Q3W, administered every 3 weeks; SC, subcutaneous; TNBC, triple-negative breast cancer.

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REGN7075

An Investigational EGFRxCD28 Bispecific Antibody
Simultaneously engages EGFR expressed by cancer cells with CD28 on T cells[1]

+

CEMIPLIMAB

An Investigational, Fully Human PD-1 Monoclonal Antibody
Designed to block cancer cells from using the PD-1 pathway to suppress T-cell activation[2]

SELECTED INCLUSION CRITERIA[a]

- ECOG PS 0 or 1
- Histologically or cytologically confirmed cancer
- Expansion cohorts only: Anti-PD-1/PD-L1 naive
- Willing to provide tumor tissue from newly obtained biopsy from tumor site not previously irradiated
- Adequate organ and bone marrow function
- Life expectancy ≥3 months

SELECTED EXCLUSION CRITERIA[a]

- Participation in another study of an investigational agent or device within 4 weeks of first dose of study treatment
- Received treatment with an systemic therapy within 4 weeks of the first administration of study treatment
- Prior treatment with anti-EGFR therapy
- Received radiation therapy within 2 weeks of first dose of study treatment
- Has second malignancy that is progressing or requires active treatment
- Untreated or active primary brain tumor, CNS metastases, leptomeningeal disease, or spinal cord compression
- Encephalitis, meningitis, organic brain disease (ie, Parkinson disease) or uncontrolled seizures within 1 year prior to the first dose of study treatment
- Any ongoing inflammatory skin disease

For more information, visit www.clinicaltrials.gov or please call [+353 (0)61 533 400 OR 844 REGN-MID].
NCT04626635
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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.

ECOG PS, Eastern Cooperative Oncology Group performance status; PD-1, programmed cell death protein-1; EGFR, epidermal growth factor receptor; RESIST, Response Evaluation Criteria In Solid Tumors; TLR9, toll-like receptor 9, CNS, central nervous system.

1. Segal NH et al. *J Clinical Oncology* 2023; 41:4_suppl 2. Markham A, Duggan S. *Drugs*. 2018;78(17):1841-1846.

Current per clinicaltrials.gov as of October 23, 2023.

CEM-EM-0025 November 2023.

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