REGENERON
SCIENCE TO MEDICINE®

Oncology Areas of Interest

(Investigator Initiated Studies and Research Collaborations)

R2810 (Cemiplimab)

Cemiplimab is available for dosing Q3W IV or Q6W IV

Types of proposals

- Combination with standard of care (SOC) including exploration of sequencing
- Studies in indications of high unmet need and unaddressed rare populations
- Novel study concepts investigating squamous histologies
- Studies incorporating ctDNA as an exploratory endpoint to generate early insights or as a key endpoint, treatment-guiding factor, or enrollment criterion in the neoadjuvant/ adjuvant/ perioperative setting (except in NMSC) may be considered on a very limited basis

NOT PREFERRED: Concomitant IO/RT

Areas of interest for NSCLC

- Stage I-III treatment settings
- Novel combinations

Areas of interest for non-melanoma skin cancer

- Novel combinations
- BCC
    - Combination studies in all treatment stages including post-anti-PD-1
    - Neoadjuvant setting (prior to surgery or RT)
    - High-risk populations
- CSCC
    - Treatment of high-risk pre-cancerous lesions and studies in post-IO settings including retreatment will be considered on a limited basis

Other tumor types

- SCLC, GI, genitourinary, and gynecological cancers will be considered on a limited basis

Note: Novel combinations must have rationale for complementary mechanisms of action using agents with established dose range and safety

(V6.0, May 2025)

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REGN3767 (anti-LAG3)_fianlimab

Note: Fianlimab is dosed at 1600 mg IV Q3W in combination with cemiplimab

Types of proposals

- Studies informing ideal patient selection and optimization of outcomes, including evaluation of contribution of fianlimab treatment
- Studies exploring the clinical activity of fianlimab + cemiplimab early in the treatment paradigm
- Studies with strong scientific rationale expected to increase understanding of LAG3 biology

NOT PREFERRED: Studies in IO-refractory setting (relapsed acceptable)

Areas of interest for melanoma

- Studies to support further understanding of the role of fianlimab + cemiplimab in melanoma including high risk populations (including brain mets, liver mets) and validated biomarker-selected populations with unmet medical need
- Studies assessing sequencing of targeted therapies and IO in BRAF-mutated patients would be considered from a coop group only

Areas of interest in other indications

- NSCLC:
    - Multi-modality treatment (i.e. combinations with radiation, systemic therapy, or other therapeutic modalities) may be considered on a limited basis
      NOT PREFERRED: studies assessing stage III unresectable NSCLC
- Non-melanoma skin cancers:
    - Studies in peri-operative CSCC or BCC may be considered on a very limited basis

NOT PREFERRED: other thoracic malignancies, hepatocellular carcinoma, HNSCC, gynecological oncology, breast cancer, primary CNS cancers, sarcoma

(V6.0, May 2025)

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REGN5093 (METxMET)_davutamig

Areas of interest for NSCLC

- Davutamig in patients with MET alterations who are unable to tolerate TKIs
- Combination studies of davutamig with TKIs (including EGFR-targeted or MET-targeted therapies) in patients with MET-amplification or overexpression
- Combination studies of davutamig with cemiplimab (anti-PD-1) in MET alterations in immune-checkpoint inhibitor-naïve populations

Areas of interest in other tumor types

- Proposals addressing other indications where MET may be a driver or a mechanism of resistance to targeted therapy will be considered on a limited basis (i.e. CRC, GI cancers, mesothelioma, papillary RCC)

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