REGENERON
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Oncology Areas of Interest

(Investigator Initiated Studies and Research Collaborations)

R2810 (Cemiplimab_Libtayo)

Types of proposals

- *Combination with standard of care (SOC) including exploration of sequencing*
- *Studies in indications of high unmet need and unaddressed rare populations*

NOT PREFERRED: Concomitant IO/RT; Studies with main focus on ctDNA/MRD

Areas of interest for NSCLC

- *Early treatment settings*
- *Combinations in IO-experienced patients*
- *Studies assessing multi-modality treatment (i.e. combinations with radiation, systemic therapy, or other therapeutic modalities) will be considered on a limited basis*

NOT PREFERRED: studies assessing stage III unresectable NSCLC

Areas of interest for non-melanoma skin cancer

- *Novel combinations with rationale for complementary mechanisms of action using agents with established dose and safety*
- *BCC*
  - *Combination studies in all treatment stages including post-anti-PD-1*
  - *Neoadjuvant setting (prior to surgery or RT)*
  - *High-risk populations*
- *CSCC*
  - *Early stage disease and post-IO settings including retreatment will be considered on a limited basis*

Other tumor types

- *SCLC and GI will be considered on a limited basis*
- *Studies in the following indications will only be considered via CTEP/coop group: breast cancer, gynecologic oncology, genitourinary, HNSCC*

Cemiplimab is available in the approved dosage form Q3W IV as well as exploration of Q6W IV

(V5.0, Aug 2024)

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Oncology Areas of Interest

(Investigator Initiated Studies and Research Collaborations)

REGN3767 (anti-LAG3)_fianlimab

Types of proposals

- *Insights to inform ideal patient selection and optimization of outcomes*
- *Studies exploring the clinical activity of fianlimab + cemiplimab early in the treatment paradigm*
- *Proposals that include contribution of components (fianlimab) are encouraged*
    - *Fianlimab dosed at 1600 mg IV Q3W in combination with cemiplimab*
- *Studies with strong scientific rationale expected to increase understanding of LAG3 biology*

NOT PREFERRED: Studies in IO-refractory setting (relapsed acceptable); Studies with main focus on ctDNA/MRD

Areas of interest for melanoma

- *Studies to support further understanding of role of fianlimab + cemiplimab in melanoma including high risk populations (including brain mets) and validated biomarker-selected populations with unmet medical need*
- *Studies in uveal melanoma will only be considered via CTEP/coop group*

Areas of interest in other indications

- *Novel approaches for treatment of liver metastases*
- *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
- *Gastro-intestinal:*
    - *CRC studies with focus on early treatment setting (neo-adjuvant or 1st line IO naïve)*
    - *Studies in gastro-esophageal cancer will be considered on a very limited basis*
- *Genito-urinary*
    - *RCC studies in 1st line combination with TKI will only be considered via CTEP/coop group*
- *Non-melanoma skin cancers:*
    - *Studies in peri-operative CSCC or BCC may be considered on very limited basis*

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

(V5.0, Aug 2024)

Oncology Areas of Interest

(Investigator Initiated Studies and Research Collaborations)

REGN5093 (METxMET)_davutamig

Areas of interest for NSCLC

- *Davutamig monotherapy in patients with MET-amplification who are unable to tolerate TKIs*
- *Combination studies of davutamig with other TKIs (including EGFR-targeted and other targeted therapies) in patients with MET-amplification or overexpression in all lines of therapy*
- *Combination studies of davutamig with cemiplimab (anti-PD-1) in MET alterations in all lines of therapy*

Areas of interest in other tumor types

- *Assessment of davutamig in other indications where MET may be a driver or a mechanism of resistance to targeted therapy, including but not limited to:*
    - *Non-clear-cell RCC, particular papillary*
    - *CRC*
    - *Gastric/upper GI cancers*
    - *Mesothelioma*
- *Biomarker strategies to inform sequencing, treatment intensification, or identification of novel or rare indications*

Combination studies of fianlimab (anti-LAG3) with cemiplimab and davutamig may also be considered in PD(L)1-naïve setting.

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