

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*
- *Novel combinations with rationale for complementary mechanisms of action using agents with established dose and safety*
- *Studies in indications of high unmet need and unaddressed rare populations*
- *Studies exploring optimizing duration of treatment*
- *Studies incorporating hypothesis-driven biomarkers for response or resistance*
- *Studies evaluating treatment practices including use of cemiplimab in real-world settings*

Areas of interest for non-small cell lung cancer (NSCLC)

- *Early treatment settings*
- *Combinations in IO-experienced patients*
- *Multi-modality treatment (i.e. combinations with radiation, systemic therapy, or other therapeutic modalities)*

Areas of interest for non-melanoma skin cancer

- *Basal Cell Carcinoma (BCC)*
 - *Combination studies in all treatment stages including post-anti-PD-1*
 - *Neoadjuvant setting prior to surgery or radiation therapy (RT)*
 - *High-risk populations*
 - *Insights on the biology of disease, genetic risk for progression, biomarkers*
- *Cutaneous Squamous Cell Carcinoma (CSCC)*
 - *Stage II disease and post-IO settings including retreatment*
- *Other rare skin tumor types (Merkel cell, adnexal tumors, skin lymphomas)*

Areas of interest for other tumor types

- *Studies addressing clinical activity and/or with broad translational implications expected to be informative of disease biology in settings of unmet need, including but not limited to:*
 - *Head and neck squamous cell carcinoma (HNSCC)*
 - *GI cancers and GU cancers (rational combinations with TKIs, VEGF inhibitors, ADCs or standard of care)*
 - *Neuroendocrine tumors including small cell lung cancer (SCLC)*
 - *Breast cancer*

Cemiplimab is available in the approved dosage form Q3W IV as well as Q6W IV in select adjuvant settings.

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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*
 - *Studies in the IO-refractory setting are not encouraged (relapsed acceptable)*
- *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*

Areas of interest for NSCLC (across all stages) and melanoma

- *Studies to support further understanding of role of fianlimab + cemiplimab in melanoma and NSCLC including:*
 - *Novel combinations with targeted or IO agents or other treatment modalities with rationale for complementary mechanisms of action and established dose and safety*
 - *High risk populations and validated biomarker-selected populations with unmet medical need*

Areas of interest in other indications

- *Studies addressing clinical activity and/or with broad translational implications expected to be informative of disease biology in settings of unmet need including but not limited to:*
 - *GU cancers: focus on early treatment setting and novel biomarker selection approaches.*
 - *GI cancers (especially CRC, gastric and esophageal): focus on early treatment setting (neo-adjuvant or 1st line IO naïve)*
 - *Other thoracic malignancies with solid scientific rationale (e.g. SCLC)*
 - *HNSCC: locally advanced HNSCC (HPV+ neoadjuvant or any non-resectable)*
 - *Advanced disease with liver metastases*
 - *Proposals for hepatocellular carcinoma (HCC) may be considered on a limited basis*

(V4.0, May2024)

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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 renal cell carcinoma (RCC), particular papillary*
 - *Colorectal cancer (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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