

## Oncology Areas of Interest

(Investigator Initiated Studies and Research Collaborations)

### R2810 (Cemiplimab\_Libtayo)

#### Areas of Interest for NSCLC:

- *Insights to inform ideal patient selection and optimization of outcomes*
- *Early treatment settings and post-IO are preferred*

#### Areas of Interest for non-melanoma skin cancer:

- *Studies in BCC*
  - *Combination studies with cemiplimab in all treatment stages including post-anti-PD-1*
  - *Cemiplimab in surgery or RT eligible patients before other systemic therapies*
  - *Cemiplimab in other pre-BCC genetic syndromes or high-risk populations*
  - *Insights on the biology of disease, genetic risk for progression, biomarkers*
- *Study proposals for other skin tumor types (CSCC, Merkel Cell, Adnexal Tumors, Skin Lymphomas) will be considered and will be evaluated with clear opportunity of benefit beyond the current standard of care*

#### Types of Proposals

- *Combination with Standard of Care (SOC) including exploration of sequencing*
- *Combination with new agents that address complementary mechanisms of action*
- *Studies in indications of high unmet need and unaddressed rare populations*
- *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:*
  - *HNSCC, GI cancers, GU cancers, breast*
- *Studies evaluating treatment practices including use of cemiplimab in real-world settings*

(V3.0, 8May2023)

### CMP-001 (TLR9)\_vidutolimod

- *Studies to support further understanding of the role of vidutolimod (+/- cemiplimab) in indications that are amenable to intralesional administration*
  - *Clinical interventional proposals in indications of CSCC, BCC, MCC and melanoma will not be considered, however clinical translational studies with strong research component are of interest*
- *Studies with strong rationale expected to increase understanding of vidutolimod biology in **\*preclinical** mouse models and in vitro studies, and translational biomarker studies*

(v1.1, 8May2023)

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### REGN3767 (anti-LAG3)\_fianlimab

#### Types of Proposals

- *Insights to inform ideal patient selection and optimization of outcomes*
- *Studies exploring the use of Fianlimab & Cemiplimab early in the treatment paradigm*
- *Studies with strong scientific rationale expected to increase understanding of LAG3 biology in **\*preclinical** mouse models and in vitro studies, and translational biomarker studies, to inform combination therapy of fianlimab + cemiplimab*

#### 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 targeted or IO combinations/modalities with solid mechanistic rationale*
  - *High risk and biomarker-selected populations with unmet medical need*
- *Studies to further explore role of LAG3 in specific unmet medical need melanoma and NSCLC populations (early treatment setting preferred)*

#### 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 (especially renal and bladder): 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 1<sup>st</sup> line IO naïve)*
  - *Other thoracic malignancies with solid scientific rationale (e.g. mesothelioma, SCLC)*
  - *HNSCC: locally advanced HNSCC (HPV+ neoadjuvant or any non-resectable) or recurrent/metastatic HNSCC (IO naïve)*

(V3.0, 16Oct2023)

### REGN5093 (METxMET)

- *METxMET monotherapy in patients who are unable to tolerate TKIs or combination studies of METxMET with TKIs (including EGFR-targeted and other targeted therapies) in MET-altered NSCLC in all lines of therapy*
- *Combination studies of METxMET with cemiplimab (anti-PD-1) in MET-altered NSCLC*
- *Assessment of METxMET in other indications where MET may be a driver or a mechanism of resistance to targeted therapy*
- *Identification of novel or rare indications using biomarker strategies*

(v1.0, 8May2023)

#### **\*Any Preclinical Research Collaborations including:**

- *Proprietary animal models, cell lines, and/or other technologies.*
- *Approved medicines or therapeutic pipeline candidates for use in non-human studies.*
- *Can submit a research proposal at [Regeneron Preclinical Research Collaborations](#)*