

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 with a focus in NMSC and NSCLC

- Combinations with standard of care (SOC), including exploration of sequencing (NOT PREFERRED: Concomitant IO/RT)
- Studies in indications or patient subpopulations of high unmet need in interventional studies, and on a very limited basis high-quality registry-based studies
- Novel approaches in early treatment settings
- Novel study concepts investigating squamous histologies
- Studies incorporating ctDNA as a treatment-guiding factor, enrollment criterion in the neoadjuvant/ adjuvant/ perioperative setting (except in NMSC), or as a key endpoint may be considered on a very 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

(V7.0, May 2026)

REGN3767 (anti-LAG3)_fianlimab

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

- The fianlimab program will consider only exceptional proposals on a very limited basis

(V7.0, Oct 2025)

CMP-001 (TLR9)_vidutolimod

Proposals for studies with vidutolimod will be considered on a very limited basis in settings with strong scientific rationale in which tumors are amenable to intralesional administration*, with focus on:

- Locally advanced disease with lesions that have not been previously irradiated
- Neoadjuvant studies
- Combination with cemiplimab**

Out of scope:

- Studies of metastatic disease or PD-1 resistant disease
- Preclinical studies

*Vidutolimod dosing is 10 mg QW x 7 doses. The first dose may be given SC or IT, with subsequent doses given IT

**Cemiplimab dosing is 350 mg IV Q3W

(v2.0, May 2026)