Pembrolizumab Funding Review Cycle 3Q2022

The following guidance is provided to facilitate preparation of competitive proposal submissions:

- The Oncology Investigator Initiated Studies Program (IISP) Committee is welcoming submissions in a second round of review for proposals seeking funding in 2022. Please note that this submission cycle has very specific Areas of Interest (AOI) and a limited number of approvals is expected. Please review the focused Areas of Interest (AOI) below.
- Please contact your local Research Medical Scientific Director (RMSD, US only) or country specific liaison for any guidance pertaining to your specific proposal prior to its submission, to ensure that it falls within the scope and interest of the Investigator Initiated Studies Program (IISP).
- The pembrolizumab Investigator Initiated Studies Program (IISP) is large with numerous approved studies, which include single agent, standard of care systemic therapies, and/or radiation combinations. Please check www.clinicaltrials.gov to ensure similar studies to your proposed concept summary are not already approved or ongoing. You may also discuss what may be possibly in development with your RMSD or country specific liaison.
- Please include documentary evidence of successful and timely accrual and publication of investigators' studies in similar indications where possible. Operational deliverability is carefully considered in our assessment process.
- The program encourages young investigators to seek guidance from a mentor in submitting IISP proposals. If working with a mentor please also provide their CV where possible, along with a detailed letter from the mentor describing the mentoring plan and how this IISP will help the investigator meet their career objectives.
- In addition, please note that proposals with safety as a sole primary endpoint will not be considered.
- The program requests that investigators specify how they will support diversity in enrollment to include traditionally underrepresented minorities/ethnic groups.

Beginning July 25, 2022, the Oncology Investigator Initiated Studies Program (IISP) Committee will accept proposal applications within our current areas of interest (AOI). For this review cycle all applicants must submit their proposal and updated CV to Visiontracker by September 30, 2022. For investigators outside of the US, please contact your MSD country liaison for relevant requirements and timelines.

The IISP review is a competitive process. Decisions will be made on the basis of scientific/clinical merit and strategic fit, as well as operational deliverability.

Please be sure to abide by the timelines for this process as outlined below when submitting applications.

The Areas of Interest for Pembrolizumab for the 3Q2022 Funding Cycle are as follows:

- Pembrolizumab in combination with an investigational agent(s). Innovative doublet or triplet combinations will be considered.
    - Proposals should be signal seeking phase 2 studies with clinical efficacy (for example, pCR, RR, PFS, EFS etc.) as the primary endpoint
    - The sample size should have statistical justification for the efficacy parameter
    - While single arm studies are preferred, a randomized phase 2 design may be considered; however, investigators should take into account sample size, duration of accrual, multi-site involvement and budgetary constraints.
    - MSD investigational pipeline agents are not currently available for use in the IIS program.
    - Investigational non-MSD agents should be sought from the appropriate third party. A letter of support from the third party with a firm commitment for drug supply is mandatory. Partial funding from the third party is highly desirable.
    - The investigational agent should have completed first in human testing and phase 2 dose should be established. Demonstrated single agent clinical activity in the tumor type of interest is highly desirable. The rationale for combination therapy with pembrolizumab should be detailed in the proposal.
    - Preference will be given to novel mechanistic combinations. For example, doublet combinations with PARP inhibitors or VEGF TKIs are generally not of interest for this round.

IISPs should not compete with or duplicate any registration trial for pembrolizumab. Additionally, since the dose, schedule and duration for pembrolizumab has been established for multiple cancers, investigation of alternate doses and schedules will not be considered.