Belzutifan

Below are the corresponding Areas of Interest (AoIs) and deadlines

Belzutifan

We are currently accepting proposals for the belzutifan Investigator Initiated Studies Program (IISP). Please be aware that this is a highly competitive process.

To help to prepare a successful proposal, we are providing the following guidance:

- Please contact your local Regional Medical Scientific Director (RMSD, US only) or country specific liaison for any guidance pertaining to your specific concept prior to its submission, to ensure that it falls within the scope and interest of the Investigator Initiated Studies Program (IISP).
- Carefully review the Areas of Interest (AOI) below. Proposals that are not within the scope of these AOIs may be rejected without further review. Occasionally, we receive proposals out of the AOIs that represent "out of the box" thinking and are ultimately of great interest. If you believe this may apply for your proposal, please review with your RMSD or appropriate liaison prior to submission.
- Please include documentary evidence of successful and timely accrual and publication of investigators' studies in similar indications where possible. Feasibility is carefully considered in our assessment process.
- Pembrolizumab may be available for combination with belzutifan provided there is a strong rationale for the combination.
- Combinations with non-MSD agents may be considered. In such cases, it is the responsibility of the investigator to procure approval for supply of third-party agents, which should be demonstrated with a letter of support.
- The Program encourages less experienced investigators to seek guidance from a mentor prior to 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.
- Proposals with safety as a sole primary endpoint are out of scope.
- Proposals for which the primary objectives are translational that are outside of the current MISP AOIs should be directed to our Oncology Translational Studies Program (OTSP) when the next cycle is available for submission. Please note that this will also include preclinical proposals (new as of December 2024).

- The program requests that investigators specify how they will include populations that have historically had limited access to care.

Please note that IISP proposals competing with or duplicating any registration trial for belzutifan will not be supported.

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

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

For investigators outside of the US, please contact your MSD country liaison for relevant requirements and timelines.

Special Note: Diversity & Inclusion and Patient Engagement

We seek to foster diverse and inclusive representation and patient engagement within the individual Areas of Interest for each tumor type. We encourage study proposals across our Program which, in addition to demonstrating scientific merit, also take into consideration the following:

- Outcome disparities in populations that have historically had limited access to care
- Inclusion of non-academic programs/institutions
- Involvement of under-represented regions or countries

2025 Areas of Interest for Belzutifan - Clinical

Pan-tumor:
Belzutifan as a single agent or in combination in the following the areas:

- VHL-disease related disease/neoplasm that has not been studied.
- Diseases or neoplasms that have VHL somatic mutations.
- Diseases with mutations to HIF2a pathway i.e., FH, SDHx, EPAS1/HIF2, ELOC/TCEB1, EGLN1. Mutations must be detected by an appropriately clinically validated test undertaken by a CLIA-accredited lab or equivalent.
- Neoplasms or other diseases where there is a strong rationale supported by preclinical and/or clinical data.
- Non-oncologic Hif-2a driven diseases.

Melanoma:

- Studies of Belzutifan in uveal melanoma in early stage as well as advanced disease, 1L and later, including post-Tebentafusp and Monosomy 3 enriched populations.