HORIZON-HLTH-2022-DISEASE-06-02-two-stage:

Pre-clinical development of the next generation of immunotherapies for diseases or disorders with unmet medical needs (RIA)

Subsidy: €6M
Funding rate: 100%
Deadline: First stage: 1 February 2022
Second stage: 6 September 2022
Duration: No limit; up to 4 years is recommended
Total budget: €60M

Consortium:

At least three legal entities established in different Member States or Associated Countries.

Projects may consider the use of the nanobiotechnology infrastructure platform of the European Commission's Joint Research Centre.

Scope

Immunotherapy is defined as a treatment able to stimulate or restore the ability of the immune (defence) system to fight infection, disease or disorder. It has proved to be a valuable medical treatment notably when preventive interventions are not available. Passive and active immunotherapies (such as antibody-based, RNA-based and cell-based therapies, respectively) are covered by this topic, which is aiming at the pre-clinical to first-in human development of next generation immunotherapies for unmet needs.

Proposals should build on existing knowledge in the field, when available, in order to save time and to avoid spilling resources, and could build on the knowledge of the interaction between the immune system (innate and adaptive arms) and the microbiota, or take advantage of key enabling technologies such as biotechnology and nanotechnology, advanced manufacturing, imaging, 5G, internet of things, artificial intelligence and existing databases.

The next generation of immunotherapies are needed in order to improve and diversify the capabilities of health care for several communicable and non-communicable diseases[1] that cannot be effectively tackled with the currently available treatments.

Proposals are expected to address some of the following research gaps for the development of the next generation of effective and safe immunotherapies:

- Preclinical development and study of new immunotherapeutic agents in vitro and in relevant animal model(s) of the disease(s). This includes understanding of the therapy's agent(s) mode of action, its toxicity, the development of related potency assay(s), and its/their validation in vitro and in vivo. A robust regulatory and Health Technology Assessment (HTA) strategy should be in place at the start of the proposal.
- Off-the-shelf therapies, including the cell-based therapies, will be considered as assets during the evaluation.
- Proposals could include proof-of-concept (PoC)/first-in-human studies for testing the new therapies, with a clear regulatory and clinical pathway[2] and should address as appropriate the therapy-related potential for adverse side effects. PoC and clinical studies in humans should take sex, gender, age and socio-economic factors into account, where relevant. Phase II studies or later phase trials will not be supported.
- Development of a standardised framework for assays and data usage to enable a robust assessment of the safety and efficacy.
- In case treatments are already available for the proposed targeted disease(s), a justification of the need for development of a new immunotherapy treatment is requested.
- The proposed action should include a pathway of the necessary steps to ensure sustainable therapeutic agent production (considering intellectual property management if relevant) and uptake by health systems and rapid access to patients.

Expected Outcome

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to some of the following expected outcomes:

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[1] Excluded from the scope are the preventive vaccines, the immunotherapies for rare diseases and the repurposing of drugs as they are covered by other topics in the HE research programme 2021-2022. Research on cancer immunotherapies is excluded as it will be covered by the Mission on Cancer.

[2] In case proposals are involving clinical studies, please use the document on essential information for clinical studies provided on the portal.

- The scientific and clinical communities make effective use of the pre-clinical validation of new immunotherapies for high burden diseases or disorders with unmet medical needs.
- The scientific and clinical communities have access to new knowledge allowing for a better understanding of the mode of action of the next generation of immunotherapies and/or combinatorial treatments, which enables further development and optimisation of treatments.
- The scientific and clinical communities have access to and use new personalized models (in vitro and in vivo) for high burden diseases or disorders as well as protocols for the next generation of immunotherapies.
- Health care professionals have access to and use new evidence-based safety and efficacy guidelines for immunotherapies. Proof-of-clinical concept, when applicable, as single or combinatorial treatment, should be compared to existing approaches.

Additional Information:

Projects may consider the use of the nanobiotechnology infrastructure platform of the European Commission's Joint Research Centre, in particular for the accurate physicochemical characterization of therapeutic proteins and antibodies.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

Projects could consider the use of the Nanobiotechnology infrastructure platform of the European Commission's Joint Research Centre, in particular for the accurate physicochemical characterization of therapeutic proteins and antibodies.