Nanomedicine therapy for cancer

Specific challenge: Promising pre-clinical nano-medicine proof-of-concepts have been developed for the therapy of cancer, but their translation into clinical therapies remains a major challenge. An important bottleneck is up-scaling under Good Manufacturing Practice (GMP) conditions for the production of the nanomedicines from the pre-clinical laboratory scale to the quantity needed for clinical testing.

Scope: The aim is to translate promising novel nano-technology enabled therapies for cancer with pre-clinical proof-of-concept, from a pre-clinical lab stage up to Phase I clinical testing. The project shall start from an established pre-clinical proof-of-concept, with relevant efficacy and toxicity data. The project shall be focused on the translation process, so that ultimately new effective therapies can be introduced to the European healthcare market. An important aspect is the development of a pilot line for scaling-up the production of the nanomedicines and the quality control, taking into account GMP and medical regulatory requirements. Projects may include the later stages of pre-clinical testing and Phase 1 clinical testing, but the latter is not a requirement. Nanopharmaceuticals may be manufactured with either a top-down or a bottom-up approach, using for example self-assembling technology. Applicants must describe, according to industrial criteria, how the various barriers for advancing their new therapy to clinical application will be overcome, including technical, IPR, competitive, commercial and regulatory criteria, with efficacy and toxicity. Attention must be paid to clinical trial design and the foreseen research and commercial path to market introduction has to be well outlined.

For this topic, proposals should include an outline of the initial exploitation and business plans, which will be developed further in the proposed project.

The research is to be implemented from TRL 4/5 and target TRL 6/7. Implemented as cross-KET activities.

The Commission considers that proposals requesting a contribution from the EU between EUR 6 and 9 million would allow this specific challenge to be addressed

appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

Potential major improvement in clinical cancer therapy, thereby providing enhanced quality of life for patients (taking gender and other diversities into account).

Potential reduced direct and indirect healthcare costs linked to the disease and its treatment.

Accelerated introduction of new nanotechnology enabled cancer therapy, through robust manufacturing and quality control procedures for new nanotechnology enabled drugs.

Type of action: Research & Innovation Actions

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