IHI Call Days | Call 9

Developing an inhalable thyroid hormone nanotherapy for regenerating the diabetic heart and kidney

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Challenges and objectives

- Diabetes affects over 425 million people worldwide, kills 3 people every minute, and costs over $825 billion per year. Two-thirds of these deaths are attributed to diabetic cardiomyopathy (DC) and diabetic nephropathy (DN).
- While current treatments can partially delay organ damage, an efficient treatment for DC and DN remains an unmet need in contemporary medicine.
- To address these challenges we have developed and patented an innovative nanoparticle-based approach to target and repair diabetes-injured cells.
- Aligned with Specific Objective 1 of the call, we will now optimize this therapeutic tool to advance it toward early clinical-stage development.

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Our approach to solve the problem

- **Problem:**

L-triioiodothyronine (T3) treatment has been proposed as a potential strategy to stimulate repair and regeneration in damaged heart and kidney tissues. However, adverse effects associated with chronic T3 administration have hindered the clinical translation of this approach.

- **Approach:**

We have developed an innovative nanoparticle-based drug delivery system (NanoT3) that targets and releases T3 in diabetes-injured cells. NanoT3 system has demonstrated high specificity, no toxicity and has significantly improved heart and kidney function following chronic administration in diabetic rats.

- **Solution:**

To advance our strategy toward clinical application, we aim to (i) optimize NanoT3 for inhalation delivery; (ii) conduct in vivo preclinical GLP toxicology studies; (iii) perform a feasibility study for GMP process development; and (iv) initiate a Phase I clinical trial to assess the safety of NanoT3.

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Suitability for IHI

To achieve an impactful health innovation through this proposal, public-private collaboration is essential: public entities will provide research expertise, while private partners will offer resources and commercialization pathways, accelerating NanoT3's journey from discovery to clinical application.

Key Industry Support for Clinical Translation:

- **Manufacturing & Scale-Up**
  (GMP production and scalable quality control)
- **Funding & Partnerships**
  (Investment and partnership support)
- **Clinical Trial Management**
  (Trial design, recruitment and monitoring)
- **Regulatory Guidance**
  (IND strategy and trial design support)
- **Safety & Toxicology Studies**
  (GLP toxicology and ADME profiling)
- **IP & Commercialization Strategy**
  (IP protection and market access planning)

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Outcomes and Impact

- **Dual Treatment for diabetic cardiomyopathy and nephropathy:** the NanoT3 targeted drug delivery system is designed to treat DC and DN simultaneously, providing a holistic approach to manage diabetes-related complications.
- **Broader Therapeutic Potential:** beyond diabetes, NanoT3 has shown promise in treating other cardiopathies, such as myocardial infarction and cardiotoxic injuries.
- **Easy translability and implementation:** NanoT3 is engineered for scalability, low-cost production, and potential inhalable delivery, facilitating smooth integration and implementation within healthcare systems, and helping to reduce chronic disease management costs.
- **Strengthening European Competitiveness:** a successful outcome would boost the European nanomedicine sector, positioning Europe as a leader in diabetes management and next-generation drug delivery systems for chronic diseases.
- **Patient-Centered Innovation:** an inhalable nanomedicine that safely and effectively treats DC and DN could greatly improve patients' quality of life, offering a convenient and non-invasive treatment option.

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Expertise and resources

Our field of expertise:

- **Mario Negri Institute for Pharmacological Research:** experimental and clinical nephrology and cardiology, regenerative medicine.
- **OZ Biosciences:** design and development of innovative drug delivery systems.
- **National and Kapodistrian University of Athens:** experimental and clinical cardiology; design and development of innovative drug delivery systems.

Through **IKOP**, we provide essential resources and specialized knowledge to advance the core research and development of NanoT3. Additionally, with **IKAA**, we can support supplementary initiatives, such as dissemination efforts, training, and broader impact studies, to maximize NanoT3's reach and integration within healthcare systems.

We are looking for:

Pharmaceutical industry partners, Biotechnology and/or Drug Delivery Technology companies, University Hospitals, Business Angels with expertise in transferring basic research discoveries to clinic, Nanotechnology and Nanomedicine companies, Biotech Incubators and Accelerators.

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