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Consortium led by eTheRNA immunotherapies Awarded EU Commission TIGER Grant of EUR 6.9 million

- ***Accelerate development of novel mRNA vaccine for hard-to-treat cancers***
- ***Clinical trial to commence end of 2021***

Niel (Belgium) eTheRNA immunotherapies NV ('eTheRNA'), a clinical-stage company developing mRNA-based immunotherapies as off-the shelf products for the treatment of cancer and infectious diseases, announces the award of a TIGER grant of EUR 6.9 million from the EU commission. The grant was awarded to a consortium led by eTheRNA and will be used to accelerate the development of a novel, potentially best-in-class therapeutic mRNA cancer vaccine for treating recurrent/metastatic Human Papillomavirus strain 16 positive ($HPV16^{+}$) cancers such as head and neck cancer, cervical cancer, anogenital cancer.

eTheRNA's mission is to develop mRNA-based immunotherapies as off-the-shelf products for the treatment of cancer and infectious diseases through its next generation mRNA vaccines development platform and its in-house manufacturing. Head and neck squamous cell carcinomas (HNSCCs) are the sixth leading cause of cancer worldwide. Early data suggests mRNA may play a key role in treating cancers and autoimmune diseases with potential mRNA market of approx. $37bn in 2030.

The Phase I/IIa trial for the mRNA vaccine will be administered either as a stand-alone therapy or supplementary to PD-1 inhibitor standard of care. Safety, immunogenicity and clinical activity are the key endpoints of the clinical program. Biomarker and Patient Reported Outcome Measure (PROM) research conducted in parallel with the study will facilitate future, informed therapeutic and care decisions by both patients and care teams. The mRNA cancer vaccine will be optimized for intravenous (IV) administration.

Safety and efficacy of the IV mRNA lipid nanoparticle (LNP) product has already been demonstrated in preclinical development studies. Furthermore, eTheRNA has proven the safety and efficacy of its mRNA cancer vaccines in previous clinical trials, albeit with the mRNA vaccine delivered via different routes of administration.

Marina Cools, VP of Clinical Development at eTheRNA, commented: "eTheRNA and its collaborators welcome the award of this grant. In addition to HPV, this collaboration will investigate the possibility of applying mRNA technologies to the treatment of other cancer indications with poorly met medical needs."

Jean-Pascal Machiels, Head of the Medical Oncology Department at the King Albert II Institute of Saint-Luc University Clinics in Brussels, commented: “The King Albert II Institute of Saint-Luc University Clinics is proud to contribute to this project with their expertise in conducting clinical trials of innovative treatments. This Horizon 2020 grant acknowledges and reaffirms the Institute’s excellence in cancer research for the benefit of patients.”

Antonella Cardone, Director of European Cancer Patient Coalition, commented: “We are very happy to be part of the eTheRNA project. Representing the largest cancer patient community in Europe, ECPC will ensure that the patients’ perspective is heard throughout the implementation of the project. We strongly advocate the involvement of cancer patients in research projects as they provide invaluable understanding of the challenges that they face throughout their cancer journey.”

The antigens comprise mRNAs encoding the HPV16 proteins E6 and E7 as well as eTheRNA’s proprietary TriMix mRNAs. TriMix acts as an adjuvant to activate dendritic cells to induce strong T-cell responses to the antigens. The mRNAs are formulated in novel patented LNPs, which prolong the half-life of the mRNA and deliver it to immunoactive antigen-presenting cells, which enhances T-cell responses. These LNPs also offer superb thermostability at 4°C.

The consortium project encompasses essential elements for preparing therapy validation in later stage clinical studies while addressing patient needs, values and choices. Scale up of GMP-production using eTheRNA’s in-house manufacturing platform for IV mRNA vaccines will enable further clinical studies.

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 945011.

Collaborators include:
1. Amsterdam UMC (Netherlands)
2. BiotechSubsidy (Belgium)
3. Ceratium B.V. (Netherlands)
4. eTheRNA immunotherapies NV (Belgium)
5. European Cancer Patient Coalition (Belgium)
6. Radiomics (Belgium)
7. SAGA Diagnostics AB (Sweden)
8. Saint-Luc University Clinics (Belgium)

About eTheRNA immunotherapies NV
eTheRNA immunotherapies NV is developing immunotherapy and vaccine products for the treatment of cancer and infectious disease from its multiple RNA, formulation and manufacturing technology platforms. The company is headquartered in Belgium and was established in 2013. Its founding shareholders include Progress Pharma and VUB. eTheRNA is supported by an international group of specialised investors; BNP Fortis Private Equity, Boehringer Ingelheim Venture Funds, Everjoy Fortune PTE. LTD, Grand Decade Development Limited, Fund+, LSP, Novalis Lifesciences, Omega Funds, PMV and Ying Zhou Enterprise Management Company Limited who share the Company’s ambition to build a world-leading company in the RNA field. To date, the Company has raised €63 million of venture funding. Further details relating to eTheRNA’s R&D pipeline can be found at https://www.etherna.be/immunotherapies-rd-pipeline/.

About TriMix
The TriMix platform comprises three mRNAs encoding proteins (caTLR4, CD40L and CD70) that work synergistically to deliver optimal activation of dendritic cells. These cells behave as immune response mediators and mobilize the immune system to attack cancer cells through inducing a T-cell response. Clinical proof of concept for TriMix-based immunotherapies has been established through a series of clinical trials demonstrating safety and clear clinical benefits in advanced melanoma patients. Additional clinical trials are planned.

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