FOR IMMEDIATE RELEASE

Safety and immune stimulation data from an intranodal delivery of TriMix mRNA, in the adjuvant melanoma study E011-MEL

Niel (Belgium), 1 June 2019 – eTheRNA immunotherapies NV (Niel, Belgium) announces that Dr. Ana Arance, Medical Oncologist at Hospital Clinic de Barcelona, will present safety and immune response data from the E011-MEL study at the ASCO (American Society of Clinical Oncology) Annual Meeting during the poster session "Developmental Immunotherapy and Tumor Immunobiology" on 01 June 2019. The study E011-MEL investigated the safety and immunogenicity of a mRNA-based immunotherapy ECI-006. ECI-006 is a combination of mRNAs encoding for the dendritic cell maturation triple mRNA TriMix together with mRNA coding for5 tumor-associated antigens, which aims to elicit an immune response against the tumor. Since the patients had been radically operated on, there was no expected, immediate clinical activity read-out.

The primary goal of the study was to study whether the injection of ECI-006 into inguinal or axillary lymph nodes was tolerable and clinically feasible. The intranodal injections were performed in the clinic under ultrasound guidance without anesthesia. There were two treatment arms, each of 10 patients. One group received a dose of 600 µg and the other a dose of 1800 µg per injection. The study was performed in centres in Belgium and Spain.

Nineteen out of 20 patients completed the treatment. One patient discontinued the study after 4 doses due to disease relapse. Administration of ECI-006 was well tolerated in all patients with no serious side effects. ELISPOT and intracellular cytokine staining were performed on T cells pre-stimulated in vitro for 10-12 days. Vaccine-induced immune responses were detected in 4/10 and 3/10 patients treated with the low and high dose, respectively.

Dr Arance commented "it is very encouraging that we see immune responses against most of the antigens used in the vaccine. Clinically this therapy was eminently well tolerated and feasible. Future studies should include patients with metastatic disease and test whether dosing with a concomitant check-point inhibitor can be additive"

Dr Bertil Lindmark, CMO of eTheRNA Immunotherapies stated "The study showed that intranodal therapy is clinically feasible and well tolerated. Specific Immune responses in 35% of the patients in the adjuvant setting gives a good basis for coming studies in metastatic melanoma on top of a checkpoint inhibitor"

INFORMATION FOR THE EDITOR

About eTheRNA immunotherapies

eTheRNA immunotherapies is a clinical-stage company delivering innovative cancer immunotherapies from its proprietary mRNA-based TriMix platform. eTheRNA's goal is to commercialise these immunotherapies to deliver long lasting clinical remission to cancer patients. eTheRNA was established in January 2013 as a spin-off from the VUB university in Belgium and is backed by international life science investors.

About TriMix

The TriMix platform, on which eTheRNA's immunotherapies are based, comprises three mRNAs encoding proteins (caTLR4, CD40L and CD70) that work 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 an extensive dataset demonstrating clear clinical benefits in advanced melanoma patients.

Contact information

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