4 MARCH 2019

eTheRNA immunotherapies completes patient enrolment for Phase Ib-study in adjuvant melanoma

Brussels – Niel (Belgium)

eTheRNA immunotherapies, a clinical-stage company developing cancer immunotherapies based on its proprietary mRNA TriMix platform, announces the completion of the high-dose cohort of its Phase 1b study (E011-MEL) evaluating ECI-006 (TriMix with tumor specific antigens) in an adjuvant setting in melanoma patients after surgical removal of lesions. The E011-MEL study confirms the feasibility of developing mRNA immunotherapy for direct injection intranodally, in addition to a previously used dendritic cell infusion-based approach.

The E011-MEL Phase 1b study was designed to evaluate intranodal (injection into the inguinal lymph nodes) administration of ECI-006 in adjuvant melanoma patients. ECI-006 is a TriMix-based immunotherapy boosted with mRNA encoding melanoma tumor-specific antigens. The study comprises a low-dose and a high-dose cohort, each enrolling 10 patients. Investigative centres were in Belgium and Spain. The objective of the study is to assess safety and tolerability of mRNA administered intranodally and to seek evidence of immune-stimulation.

Completion of enrolment of the low-dose cohort was reported previously in March 2018, along with initial safety data. No adverse safety signals were observed in the low-dose cohort, which has already completed its dosing phase.

Today, the company reports completion of patient recruitment for the high-dose cohort. No adverse safety signals were observed in the high-dose cohort either. Results from the immunomonitoring of the immunological responses elicited by ECI 006 will be presented at a later date.

Dr. Bertil Lindmark, Chief Medical Officer, eTheRNA immunotherapies commented: “With this study we have shown that intranodal injection of an mRNA based immunostimulatory vaccine is clinically feasible and well tolerated. This is an important result as it advances our strategy to develop mRNA based immunotherapies to treat patients with cancer. The ECI-006 can effectively induce immune priming so that we may see amplified efficacy when combined with a checkpoint inhibitor”

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 and 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 and ECI-006

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. ECI-006 contains TriMix and mRNA coding for tumor associated antigens, which have been chosen to elicit immune response in melanoma. Preclinical data suggest that TriMix based immunostimulation may elicit additive or possibly synergistic effect when combined with an immune checkpoint inhibitor.