



InteRNA Technologies Receives Regulatory Approval for Initiation of Phase I Clinical Trial of INT-1B3 in Patients with Advanced Solid Tumors

-- First-in-human trial will test the safety, pharmacokinetics and preliminary efficacy of microRNA therapeutic candidate INT-1B3 --

Utrecht, The Netherlands, May 6, 2020 – InteRNA Technologies announced today regulatory approvals in the Netherlands and Belgium for the initiation of the first-in-human (Phase I) clinical trial testing its lead microRNA candidate, INT-1B3, in patients with advanced solid tumors. INT-1B3 is a lipid nanoparticle (LNP) formulated, chemically modified miR-193a-3p mimic that can be delivered by systemic administration to cancer cells. Due to the ongoing COVID-19 pandemic, clinical trial initiation has been delayed and is now anticipated to start during H2 2020. The Company will provide an update once the trial has officially launched.

The study is a multicentric, open-label and multiple ascending dose clinical trial that will investigate the safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of INT-1B3 in patients with advanced solid tumors. The study is expected to enroll a total of up to 80 patients at 12 clinical centers in the United States and Europe. The first part of the trial is a Phase Ia dose escalation study, conducted in the Netherlands and Belgium, which will enroll approximately 30 patients with advanced solid tumors. These patients will receive INT-1B3 via infusions twice weekly in 21-day cycles. Subsequently, approximately 50 patients with either hepatocellular carcinoma or triple negative breast cancer will be enrolled in the Phase Ib dose expansion part of the trial. Initial data readout from the Phase Ia study is expected in the end of 2021.

“The multi-targeted nature of microRNAs represents a novel approach to treating a broad range of cancer indications by effectively targeting several biochemical pathways simultaneously,” said Dr. Roel Schaapveld, CEO of InteRNA Technologies. “Driven by the promise of microRNAs as a treatment modality in cancer, our understanding of the underlying mechanism of action of INT-1B3 and the identification of a delivery vehicle for optimized performance, our primary focus has been on preparing our lead candidate for first-in-human clinical trials. As such, we are truly excited to bring INT-1B3 into the clinic and to gain deeper insights on how it reacts against solid tumors.”

“INT-1B3 is a promising and novel anti-cancer approach with anti-tumor potential involving direct effects on tumor cells and modulation of the immunosuppressive tumor microenvironment leading to immune system activation,” added Prof. Dr. Emile Voest, Chairman of InteRNA’s Scientific Advisory Board and Medical Director of the Netherlands Cancer Institute in Amsterdam. “The safety profile and significant anti-tumor efficacy demonstrated in preclinical studies provide a strong basis for first-in-human studies with INT-1B3.”



About INT-1B3

INT-1B3's unique mechanism of action addresses multiple hallmarks of cancer simultaneously. It directly targets tumor cells and the tumor microenvironment by specific modulation of multiple signaling pathway components across the PTEN tumor suppressor pathway and the oncogenic PI3K/Akt and Ras/MAPK pathways resulting in cell cycle arrest, induction of apoptosis and immunogenic tumor cell death (ICD); as well as downregulation of the adenosine-A2A receptor pathway and immunosuppressive FoxP3/Lag3 T_{regs} and monocytic myeloid-derived suppressor cells (mMDSCs). As a result, the immune system is activated, and long-term immunity is triggered by recruitment of CD8⁺ T_{effs} leading to decreased metastasis development and improved animal survival compared to anti-PD1 treatment. The created T cell-mediated immune response activity is also transferrable to naive mice via adoptive T cell transfer.

About InteRNA Technologies

InteRNA is developing a pipeline of proprietary preclinical microRNA drug candidates targeting key processes in initiation and progression of human diseases, with a focus on cancer. Enabled with a 3rd generation drug delivery formulation, these microRNA compounds can mount a coordinated anti-cancer attack by engaging multiple signal transduction targets simultaneously. With this approach, we address the high need for novel therapeutics with improved efficacy and less prone to drug-acquired resistance that will benefit cancer patients.

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