InteRNA Technologies Announces Dosing of First Patient in First-in-Human Trial of microRNA Drug Candidate INT-1B3 in Patients with Advanced Solid Tumors

-- Phase 1 study to investigate safety and preliminary efficacy of lead candidate, INT-1B3 --

Utrecht, The Netherlands, February 16, 2021 – InteRNA Technologies announced today that the first patient has been dosed in the first cohort of its first-in-human Phase I study with the Company's lead microRNA candidate, INT-1B3. The trial will evaluate safety and initial signs of efficacy of INT-1B3, a microRNA-mimic of the endogenous tumor suppressor miR-193a-3p formulated in next-generation lipid nanoparticles, in patients with advanced solid tumors. INT-1B3 represents a promising novel therapeutic approach that could address multiple hallmarks of cancer simultaneously by directly targeting tumor cells and the tumor microenvironment by specific modulation of multiple relevant signaling pathway components triggering a long-term T cell-mediated immune response against the tumor.

"The enrollment of the first patient in this trial, especially during the ongoing COVID-19 pandemic, is a significant milestone for InteRNA," said Dr. Roel Schaapveld, CEO of InteRNA Technologies. "microRNAs represent a new class of therapeutic agents that have the potential to change the treatment paradigm in immune-oncology, delivering a combination approach as a single regimen. We are very pleased that the first patient completed the first cycle without dose-limiting toxicity, and enrolment of the second cohort could already be initiated. The trial will allow us to generate further important insights on the potential and underlying mechanisms of INT-1B3 and reinforces our commitment to bringing this novel modality to patients, especially for the treatment of hard-to-treat solid tumors."

This two-part, open-label, multiple ascending dose Phase I/Ib trial (NCT04675996) will evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of INT-1B3. The dose escalation part of the study (part 1) will be conducted in trial sites located in the Netherlands and Belgium and will enroll approximately 30 patients with advanced solid tumors. The dose expansion part of the trial (part 2) will be conducted in multiple clinical study centers located in several European countries as well as in the United States and will enroll up to 50 patients with hepatocellular carcinoma or triple negative breast cancer. All patients will receive INT-1B3 via infusions twice per week in 21-day cycles. Topline results from the dose escalation part of the study are expected by the end of 2021.

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 inhibition of proliferation and migration and induction of cell cycle arrest and apoptosis. The triggering of the immunogenic tumor cell death (ICD) process as well as downregulation of the adenosine-A2A receptor pathway through inhibition of CD39/CD73 leads to a decrease in immunosuppressive FoxP3/Lag3 regulatory T cells and monocytic myeloid-derived suppressor cells (mMDSCs), and maturation of dendritic cells. As a result, the immune system is activated, and long-term immunity is triggered by recruitment of

CD8+ effector T cells leading to decreased metastasis development and improved animal survival compared to anti-PD1 treatment in preclinical models.

About InteRNA Technologies

InteRNA is a Dutch clinical-stage biotech company developing a pipeline of proprietary microRNA (miRNA) therapeutics targeting key processes in initiation and progression of human diseases, with a focus on cancer. Selected through InteRNA's leading miRNA discovery and functional validation platform and enabled with a 3rd-generation drug delivery formulation, these miRNA 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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