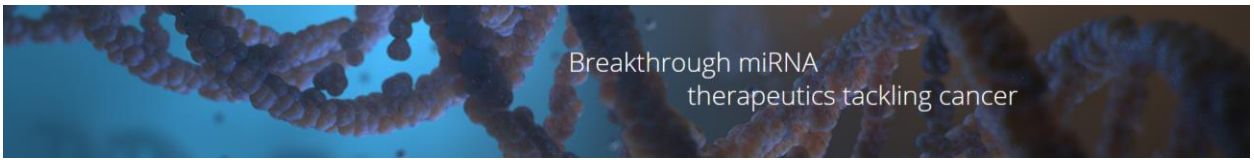
CATO SMS Signs Agreement with InteRNA to Facilitate Phase I Solid Tumor Trial



Utrecht and Schiphol, the Netherlands (19 May 2020) – InteRNA Technologies B.V. ("InteRNA") and CATO SMS ("CATO SMS"), a full-service regulatory and clinical CRO specialized in oncology, today announced that both organizations signed an agreement in which CATO SMS will conduct the Phase I clinical trial with microRNA mimic INT-1B3 in patients with advanced solid tumors.

InteRNA is advancing its lead compound INT-1B3 into the clinic. INT-1B3 is a chemically modified miR-193a-3p mimic that holds great promise based on its unique mechanism of action addressing 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.

Following successful completion of preclinical and toxicology studies, the Dutch biotech designed a multicentric, open-label, multiple ascending dose, first-in-human (FIH) Phase I clinical trial to investigate the safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of INT-1B3 in patients with advanced solid tumors. Up to 80 patients are to be enrolled in 12 sites in Europe and the US. Full regulatory approval has been obtained from local and central Ethics Committees as well as Competent Authorities for the Phase Ia dose escalation phase that will be run in the Netherlands and Belgium.

Roel Schaapveld, CEO of InteRNA: *"Advancing INT-1B3 into the clinic is exciting and represents a great opportunity for our lead compound to address an ongoing unmet medical need. We look forward to continuing to work with CATO SMS following the successful clinical trial application (CTA)-enabling activities and site selection completed in the past few months."*

Philine van den Tol, President, Clinical Trial Operations at CATO SMS*: "We are enthusiastic to continue our successful collaboration with InteRNA and are prepared to support the execution of this global, early phase clinical trial evaluating microRNA as a potential new treatment option for cancer patients."*

About InteRNA: InteRNA is developing a pipeline of proprietary preclinical microRNA drug

About CATO SMS: CATO SMS is a full-service clinical and regulatory contract research

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.

organization (CRO), specializing in complex areas such as (immuno-)oncology, advanced therapeutics and orphan diseases. CATO SMS has a center of excellence solely dedicated to oncology. With over 320 dedicated professionals with offices and operations in over 25 countries around the globe, the company brings a powerful blend of capabilities focused on supporting small and mid-sized biotech, top-tier pharmaceutical companies and investigator groups with their innovative research. We offer regulatory consulting and oncology drug development affairs in addition to clinical trial management services, with offices strategically located in close proximity from the FDA and EMA.

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