FOR IMMEDIATE RELEASE

MiNA Therapeutics Announces Initiation of Phase I Clinical Study of MTL-CEBPA in Combination with anti-PD1 Checkpoint Inhibitor in Patients with Advanced Solid Tumours

--TIMEPOINT study expands pioneering results of MTL-CEBPA in liver cancer into additional cancer patient populations--

London, United Kingdom, March 3, 2020 – MiNA Therapeutics, the pioneer in RNA activation therapeutics, announced today the initiation and first patient treated in TIMEPOINT, a global Phase 1/1b clinical study of MTL-CEBPA in combination with anti-PD1 checkpoint inhibitor pembrolizumab in patients with advanced solid tumours. The study is designed to assess the safety, tolerability, pharmacology and clinical activity of MTL-CEBPA in combination with pembrolizumab in these patients. MTL-CEBPA is the first therapy to specifically up-regulate CCAAT/enhancer binding protein alpha (C/EBP-α), a transcription factor that acts as a master regulator of myeloid cell lineage determination and differentiation. The drug candidate is also being investigated in an ongoing multi-centre Phase 1b clinical trial in patients with advanced liver cancer in combination with sorafenib.

“Initiation of the Phase I TIMEPOINT clinical trial emphasizes the continued exploration of MTL-CEBPA, the first drug candidate that targets C/EBP-α, a master regulator of immune cells that play a critical role in tumour resistance,” commented Robert Habib, CEO of MiNA Therapeutics. “We are excited to take the next step and test MTL-CEBPA in additional cancer populations in a potentially synergistic combination with an anti-PD1 checkpoint inhibitor. We look forward to collaborating with our clinical investigators in evaluating this new combination.”

The TIMEPOINT study consists of a dose-escalation followed by a dose expansion. MTL-CEBPA will be administered as an intravenous infusion once weekly in cycles of three weeks of treatment followed by one week of rest. In pre-clinical studies MTL-CEBPA has been shown to improve the anti-tumour activity of anti-PD1 checkpoint inhibition by reducing immune suppression from dysregulated myeloid cells in the tumour microenvironment.

The single agent activity of MTL-CEBPA in 39 patients with advanced liver cancer was previously presented by investigators at the European Society for Medical Oncology (ESMO) 2019 Congress. MTL-CEBPA was found to be well tolerated, demonstrating pharmacodynamic target engagement and a reduction of suppressive immune cells in the tumour microenvironment. In addition, MTL-CEBPA demonstrated clear, synergistic activity in patients with liver cancer when also treated with sorafenib standard of care.

“MTL-CEBPA has shown real promise as a combination agent in patients with liver cancer and pre-clinical studies suggest that MTL-CEBPA may also be an attractive agent to enhance the benefits of checkpoint inhibitors,” commented Professor Ruth Plummer, Clinical Professor of Experimental Medicine at the Clinical and Translational Research Institute, Newcastle

University Centre for Cancer, and Chief Investigator of the study. “We are looking forward to evaluating this highly innovative combination treatment in the upcoming Phase I trial. We hope this combination could become an effective new treatment option for patients with solid tumour cancers.”

About the TIMEPOINT Study

TIMEPOINT is a global Phase I/Ib clinical study in patients with solid tumour malignancies that will assess the safety and tolerability of MTL-CEBPA in combination with pembrolizumab in patients who are ineligible or resistant to standard therapies. The study has received clearance from the U.S. Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). To learn more about the TIMEPOINT clinical study, please visit our listing at clinicaltrials.gov.

About MTL-CEBPA

MTL-CEBPA is the first therapy to specifically up-regulate CCAAT/enhancer binding protein alpha (C/EBP-α), a transcription factor that acts as a master regulator of myeloid cell lineage determination and differentiation. Dysregulated myeloid cells have been implicated in several diseases and identified as a critical barrier for many therapies to induce clinical responses in solid tumour cancers. In pre-clinical studies MTL-CEBPA has been shown to improve the anti-tumour activity of cancer therapies by targeting dysregulated myeloid cells and reducing their suppression in the tumour microenvironment.

About MiNA Therapeutics

Harnessing an innate mechanism of gene activation, MiNA Therapeutics' platform enables the development of new medicines that restore normal function to patients’ cells. We are applying our technology and clinical know-how to transform the therapy landscape of cancer and other severe diseases. www.minatx.com

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