MiNA Therapeutics Presents Late-Breaking Positive Phase 1b Data for MTL-CEBPA in Combination with an Anti-PD1 Checkpoint Inhibitor at the Annual American Association of Cancer Research (AACR) Meeting

Findings validate clinical proof of mechanism of MTL-CEBPA as a combination therapy in solid tumor cancers

Company to initiate out-licensing activities of its immuno-oncology portfolio, including MTL-CEBPA

London, United Kingdom, 14 April 2023 – MiNA Therapeutics Limited, the pioneer in small activating RNA (RNAa) therapeutics, will present positive updated biomarker data from its Phase 1a/b TIMEPOINT study of MTL-CEBPA in combination with the anti-PD1 checkpoint inhibitor, pembrolizumab, in adults with advanced solid tumors at the annual meeting of the American Association of Cancer Research (AACR) in Orlando, Florida. Findings from the Phase 1b portion of the study validate the clinical proof of mechanism of MTL-CEBPA as a combination treatment and identify a novel predictive biomarker of clinical response. The data will be presented on Tuesday, April 18 during a late-breaking research session beginning at 9:00 am EDT.

MTL-CEBPA is the first therapy that specifically up-regulates CCAAT/enhancer binding protein alpha (C/EBP-α), a transcription factor that acts as a master regulator of myeloid cells. Dysregulated myeloid cells are implicated in several diseases including solid tumor cancers. MTL-CEBPA is designed to improve the effectiveness of checkpoint inhibitors and other immunotherapies by enhancing the body's immune response and ability to attack the cancerous cells. Interim data from an open-label, multi-center study demonstrated the safety, tolerability, immunological and clinical activity of MTL-CEBPA in combination with pembrolizumab.

"Anti-PD1 checkpoint inhibition has significantly advanced the treatment of cancer, but many patients are resistant to treatment and present with tumors that resemble an 'immune-desert'," said Robert Habib, CEO of MiNA Therapeutics. "The updated analysis of TIMEPOINT shows that MTL-CEBPA used in combination with anti-PD1 checkpoint inhibitors profoundly reprograms the tumor microenvironment, reducing resistance and enabling infiltration of disease-fighting T-cells."

The TIMEPOINT study also identified a novel predictive biomarker of clinical response to the combination treatment, presenting an opportunity for further evaluation as a potential companion diagnostic. The novel biomarker predicted clinical response across multiple tumor types.

MiNA plans to explore out-licensing opportunities for its immuno-oncology portfolio, which uniquely combines the capability to specifically restore or boost any dysregulated gene target with clinically validated *in vivo* delivery to myeloid immune cells.

MiNA's immuno-oncology portfolio includes the following programs:

- MTL-CEBPA, which has been cleared for evaluation in a global Phase 2 clinical trial in combination with the tyrosine kinase inhibitor, sorafenib, in advanced hepatocellular carcinoma (HCC or liver cancer) and in a Phase 1 clinical trial in pediatric patients with MPS1 Hurler Syndrome
- MTL-STING currently in pre-clinical development
- Additional programs currently in discovery

About TIMEPOINT
TIMEPOINT is a global Phase 1a/b clinical study in patients with solid tumor malignancies to 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, visit ClinicalTrials.gov (NCT04105335).

The poster presentation at AACR entitled, “MTL-CEBPA in combination with pembrolizumab converts an immune desert to an inflamed TME in solid tumors resistant to checkpoint blockade,” will be available on MiNA’s website in the Publications section under "RNA Activation".

About MTL-CEBPA
MTL-CEBPA is the first therapy that specifically up-regulates 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 in solid tumor cancers these cells have been identified as a critical barrier to induction of clinical response for many therapies. In pre-clinical studies, MTL-CEBPA has been shown to improve the anti-tumor activity of cancer therapies by targeting dysregulated myeloid cells and reducing or eliminating their suppressive effect on immune response and therapies in the tumor microenvironment.

About MiNA Therapeutics
MiNA Therapeutics is the global leader in small activating RNA therapeutics or RNAa. Harnessing innate mechanisms of gene activation, RNAa therapeutics are a revolutionary new class of medicines that can restore or boost normal function of genes and thereby protein-modulated pathways in patients' cells. We are advancing a proprietary pipeline of new medicines with an initial focus on genetic medicine, while collaborating with leading pharmaceutical companies to apply our technology platform across a broad range of other therapeutic areas. Based on our unique know-how in RNA activation, we are expanding the possibilities of RNA-based medicine for patients. www.minatx.com

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