

**MiNA Therapeutics presents positive Phase 1b data on MTL-CEBPA  
in combination with anti-PD1 checkpoint inhibitor**

*Clinical proof of mechanism established as an anti-cancer immunotherapy combination*

*Tumour responses observed in indications with primary resistance to checkpoint inhibitors*

**London, United Kingdom, 11 November 2022** – MiNA Therapeutics Limited (“MiNA” or the “Company”), the pioneer in small activating RNA (RNAa) therapeutics, presents positive data from its Phase 1a/b TIMEPOINT study of MTL-CEBPA in combination with pembrolizumab in adult patients with advanced solid tumours. The data demonstrates safety, tolerability and immunological and clinical activity of the combination treatment. The data will be presented at a poster session on 11 November 2022 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in Boston, entitled, ‘*Interim results for Phase 1b dose expansion of MTL-CEBPA in combination with pembrolizumab in patients with advanced solid tumour malignancies.*’

**Professor Ruth Plummer, Clinical Professor of Experimental Medicine at the Translational and Clinical Research Institute, Newcastle University, and Chief Investigator of the study, commented:**

*“Combination treatment with MTL-CEBPA represents a highly innovative approach for the majority of patients who have primary resistance to checkpoint inhibitors. I am encouraged by the clear and beneficial immunological changes observed in the tumour microenvironment of treated patients as well as the signals of clinical activity observed in patients with difficult to treat tumour types. The findings from this study support Phase 2 evaluation of the combination treatment.”*

**Robert Habib, CEO of MiNA Therapeutics, commented:**

*“The data presented at SITC establishes strong foundations for the evaluation of MTL-CEBPA as a combination treatment with checkpoint inhibitors in a range of cancer indications. In parallel with our ongoing Phase 2 clinical trial in liver cancer in combination with a tyrosine kinase inhibitor, we will explore collaborative opportunities to evaluate MTL-CEBPA in selected additional indications in combination with checkpoint inhibitors.”*

MTL-CEBPA is designed to improve the effectiveness of checkpoint inhibitors and other anti-cancer therapies by counteracting a key cancer immune evasion pathway. Previously reported [pre-clinical and clinical data](#) demonstrated that MTL-CEBPA inhibits immune suppression by myeloid cells, and in combination with anti-PD1 checkpoint inhibitor reprograms the tumour microenvironment and improves tumour growth inhibition in tumour models.

Interim data presented at [SITC](#) from the Phase 1a/b, first-in-human, open-label, multicenter TIMEPOINT study demonstrates the safety, tolerability and immunological and clinical activity of MiNA’s lead candidate, MTL-CEBPA in combination with pembrolizumab, an approved anti-PD1 (programmed death receptor-1) checkpoint inhibitor. The study enrolled 50 patients with advanced solid tumour types for which anti-PD1 checkpoint inhibitors are not approved therapies. 10 patients were enrolled in the Phase 1a dose escalation and 40 patients were enrolled in the Phase 1b dose expansion.

The combination was generally well tolerated and no dose-limiting toxicities were identified. No patients discontinued MTL-CEBPA treatment due to safety issues. The mechanism of action of the combination treatment was validated by significant changes in the tumour microenvironment of treated patients. Amelioration of immune suppression and markedly improved infiltration of cytotoxic T-cells were observed in treated patients. Confirmed objective tumour responses were observed in four treated patients with advanced ovarian cancer, malignant pleural mesothelioma, biliary tract cancer and neuroendocrine tumours.

The Company will explore opportunities to evaluate MTL-CEBPA in combination with checkpoint inhibitors in one or more Phase 2 studies in collaboration with industry partners.

MTL-CEBPA is the first drug candidate to be advanced from MiNA’s internal pipeline of RNAa therapeutics. MTL-CEBPA is currently being evaluated 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 pre-clinical development in MPS1 Hurler Syndrome. RNAa therapeutics are a revolutionary new class of medicines that can restore or boost normal function within patients' cells by selectively activating genes.

The poster presented at SITC will be made available on the Company's website in the Publications section under "RNA Activation".

#### **About the TIMEPOINT study**

TIMEPOINT is a global Phase 1a/1b clinical study in patients with solid tumour 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, please visit our listing at [clinicaltrials.gov](https://clinicaltrials.gov).

#### **About MTL-CEBPA**

MTL-CEBPA is the first therapy that specifically up-regulates CCAAT/enhancer binding protein alpha (C/EBP- $\alpha$ ), 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 tumour 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-tumour activity of cancer therapies by targeting dysregulated myeloid cells and reducing or eliminating their suppressive effect on immune response and therapies in the tumour micro-environment. MTL-CEBPA is currently in clinical development in three different studies as a combination therapy for the treatment of both first- and second-line advanced liver cancer and for a variety of advanced solid tumour malignancies.

#### **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 diseases and cancer, 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](http://www.minatx.com)

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