MiNA Therapeutics highlights clinical data supporting the further development of MTL-CEBPA as an anti-cancer immunotherapy

Positive Phase 1a data presented at SITC demonstrates safety, tolerability and clinical activity of MTL-CEBPA in combination with pembrolizumab, supporting continued development in solid tumour malignancies

Positive translational data published in Clinical Cancer Research demonstrates MTL-CEBPA's immunological mechanism of action across different tumour models and in liver cancer patients

London, United Kingdom, 12 November 2021 – MiNA Therapeutics Limited ("MiNA" or the "Company"), the pioneer in small activating RNA (saRNA) therapeutics, announces positive safety data from the Phase 1a/b TIMEPOINT study of MTL-CEBPA in combination with pembrolizumab in adult patients with advanced solid tumours. The data will be initially presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting, taking place on 10-14 November 2021. Separately, MiNA also highlights the publication of positive data in the peer-reviewed journal Clinical Cancer Research, demonstrating MTL-CEBPA's mechanism of action across different tumour models and in cancer patients.

Robert Habib, CEO of MiNA Therapeutics, commented:
"The data presented at SITC and published in Clinical Cancer Research further adds to the strong foundation of clinical evidence we have established for MTL-CEBPA. Multiple studies across different tumour models and in cancer patients have demonstrated the unique immunological effects of MTL-CEBPA and its role as a potential combination treatment in cancer. We are excited to progress into Phase 1b the development of MTL-CEBPA in patients with solid tumour malignancies."

Data presented at SITC from the ongoing Phase 1a/b, first-in-human, open-label, multicenter TIMEPOINT study demonstrates the safety and tolerability of MiNA's lead candidate, MTL-CEBPA in combination with pembrolizumab, an approved anti-PD-1 (programmed death receptor-1) checkpoint inhibitor. The study is enrolling patients with advanced solid tumour treatment settings in which anti-PD-1 checkpoint inhibitors are not approved therapies.

At the three dose levels tested, the combination was generally well tolerated, with no dose-limiting toxicity and no serious adverse events observed. Encouragingly, anti-tumour activity was also observed in three patients. These included two confirmed partial responses in patients with advanced ovarian cancer and malignant pleural mesothelioma. The data package to date supports the continuation of this programme and MiNA is currently enrolling patients into a Phase 1b dose expansion cohort, which will additionally assess immunological changes as well as clinical activity of the combination treatment. Analysis of approximately 40 patients in the Phase 1b dose expansion cohort is expected to complete in the second half of 2023.

Additionally, translational proof-of-concept data further establishing MTL-CEBPA's mechanism of action was recently published in the peer-reviewed journal Clinical Cancer Research. The data demonstrated that therapeutic up-regulation of C/EBP-α by MTL-CEBPA caused inactivation of immune-suppressive myeloid cells, potentiating anti-tumour responses in patients with advanced primary liver cancer (hepatocellular carcinoma (HCC)), as well as in several pre-clinical tumor models, including liver cancer, lung carcinoma, and colon adenocarcinoma.

This data provides evidence to support the role of MTL-CEBPA to counteract a key cancer immune evasion pathway by inhibiting immune suppression by myeloid cells, and for the potential of MTL-CEBPA in combination treatment with immunotherapies across multiple tumour types. This data also supports MiNA's strategy in liver cancer, where the Company is investigating MTL-CEBPA in patients with advanced HCC in combination with sorafenib (standard-of-care multi-kinase inhibitor), with a randomised Phase 2 clinical trial (OUTREACH-2) expected to initiate around the end of 2021.

Both the poster presented at SITC and paper published in Clinical Cancer Research 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 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 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 tumour cancers have been identified as a critical barrier for many therapies to induce clinical responses. 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 suppressive effect in the tumour micro-environment. MTL-CEBPA is currently in clinical development as a combination therapy for the treatment of advanced liver cancer and advanced solid tumour malignancies.

About MiNA Therapeutics
MiNA Therapeutics is the leader in small activating RNA therapeutics. Harnessing innate mechanisms of gene activation, small activating RNA therapeutics are a revolutionary new class of medicines that can restore or boost normal function in patients' cells. We are advancing a proprietary pipeline of new medicines with an initial focus on cancer and genetic diseases, while collaborating with leading pharmaceutical companies to apply our technology platform across a broad range of 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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