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MiNA Therapeutics Presents Top Line Results from Phase Ib Study of MTL-CEBPA in Combination with Sorafenib in Liver Cancer at 2020 ASCO Annual Meeting

--Observed clinical activity, including durable and complete tumour responses, suggests that MTL-CEBPA may increase the effectiveness of sorafenib standard of care--

--Results confirm safety and tolerability of MTL-CEBPA and sorafenib combination and support continued development in liver cancer--

London, United Kingdom, May 29, 2020 – MiNA Therapeutics, the pioneer in RNA activation therapeutics, announced today top line results from the Phase Ib dose escalation and cohort expansion study, OUTREACH, of lead candidate MTL-CEBPA in combination with sorafenib standard of care in patients with advanced hepatocellular carcinoma (HCC or liver cancer). The study met its primary endpoints of safety and tolerability for MTL-CEBPA administered either concomitantly or sequentially with sorafenib. In addition, five patients experienced objective tumour responses, including two complete responses during the combination treatment. The data will be presented during a poster session at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting, held virtually from May 29 - May 31, 2020.

"We are delighted to have confirmed objective tumour responses in a Phase Ib study in advanced liver cancer patients who are poorly served by existing treatments," commented Robert Habib, CEO of MiNA Therapeutics. "Combined with previous positive results, these data suggest that by reducing immune suppression in the tumour microenvironment, MTL-CEBPA may increase the effectiveness of sorafenib standard of care."

At the data cut-off of February 1, 2020, 36 patients with advanced HCC had been treated with MTL-CEBPA in combination with sorafenib in the Phase Ib study. 22 patients received MTL-CEBPA and sorafenib concomitantly, and 14 patients received the two agents sequentially. Both concomitant and sequential treatment regimens were generally very well tolerated, and no maximum tolerated dose was determined. The profile of adverse events was consistent with the known safety profile of each agent and the underlying disease. In addition, concomitant sorafenib treatment did not alter the pharmacokinetics of MTL-CEBPA. Five patients who were naïve to prior tyrosine kinase inhibitor (TKI) treatment experienced objective tumour responses, including two patients who experienced complete remission. Tumour responses were most pronounced in those TKI naïve patients with viral aetiology, where four out of nine evaluable patients experienced objective responses.

Treatment was associated with a reduction in both the number of immature immune suppressor cells as well as genetic markers of immune suppression in patient samples. These biomarker data validate the mechanism of action of MTL-CEBPA in reducing immune suppression, which has been identified as a resistance mechanism of solid tumours to cancer treatment, including sorafenib.

These encouraging Phase Ib data add to the previously published positive Phase I results in which four out of five patients experienced a durable, objective response to off-study sorafenib treatment after discontinuation of MTL-CEBPA. As a single agent treatment, sorafenib is associated with a very low objective response rate. In a recent Phase III study, complete responses were observed in 1% of patients and partial responses were observed in 6% of patients based on RECIST 1.1 criteria in 372 patients[1].

The poster will be made available on the "Publications" page of MiNA's website.

Presentation information
Title: Phase Ib dose escalation and cohort expansion study of the novel myeloid differentiating agent MTL-CEBPA in combination with sorafenib in patients with advanced hepatocellular carcinoma (HCC)
Abstract no: 4601
Session: Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary
Date / time: Friday, May 29, 2020 / 8:00 am Eastern Time

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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[1] Yau et al. CheckMate 459: A Randomized, Multi Center Phase 3 Study of Nivolumab vs Sorafenib as First Line Treatment in Patients With Advanced Hepatocellular Carcinoma. Annals of Oncology, Volume 30, Supplement 5, October 2019