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Cytora Reports Phase 1 Data of Stem Cell Treatment for Multiple System Atrophy

Clinical data of Cytora's oral mucosa stem cells treatment shown to be safe and may be efficient as a disease modifying therapy in moderate stages of Multiple System Atrophy

Clinical and preclinical data presented at International MSA CONGRESS, BOSTON, 2025

Yokneam, Israel, May 19 - Cytora, a clinical stage company developing unique stem cell treatments based on human Oral Mucosa Stem Cells (hOMSC), reported today data of an ongoing Phase 1 clinical study for treating moderate and advanced Multiple System Atrophy (MSA) with hOMSC300, its investigational, allogeneic, off-the-shelf, cell therapy product. The safety data collected to date demonstrate that intrathecal administration of hOMSC is safe. In addition, preliminary efficacy data suggest that hOMSC may be efficient as a disease modifying therapy in moderate stages of MSA. The interim results of the clinical trial as well as preclinical results from a mouse model of MSA were presented at the International MSA CONGRESS, BOSTON 2025.

"MSA is a debilitating, progressive neurodegenerative disease, which currently has no treatment," said Yona Geffen, PhD, CEO of Cytora. "We are therefore very encouraged by these preliminary safety and efficacy data, demonstrating that intrathecal administration of hOMSC is safe, and may be efficient in attenuating disease progression in moderate stages of MSA. We have previously reported the successful results of a Phase 1/2a clinical study for treating chronic hard to heal diabetic foot ulcers using hOMSC200, based on our proprietary stem cell platform, and we are looking forward to further advancing both of these promising indications, for the benefit of patients around the world."

The ongoing first-in-human, open label, single center Phase 1 study is aimed at testing the safety of hOMSC300 following intrathecal administration in patients with moderate or advanced stages of MSA with subsequent 18 months follow-up. For the analysis, the eight patients receiving the high dose were allocated to two groups according to their disease stage. Four patients with Unified Multiple System Atrophy Rating Scale (UMSARS) ≤20 points at baseline were allocated to the moderate stage group. Four patients with UMSARS > 20 points at baseline were allocated to the advanced stage group. Recruited subjects were administered intrathecally with either a low or a high single dose of hOMSC300. The first two patients in advanced stages of the disease were treated with the low dose. UMSARS scores were assessed.

To date, 3-18 months after hOMSC administration, no serious adverse events related to the hOMSC300 administration were recorded during this period. Treatment with hOMSC300 showed potential efficacy in patients with moderate disease, whose disease did not significantly progress at the 3, 6 and 9 months post injection period, as assessed by the UMSARS scale, with a mean change of 1.5, 1.8 and 2 points at 3, 6 and 9 months follow-up, respectively. For comparison, a multicenter cohort study of MSA from The Japan MSA registry study from 2023 shows that after 12 months there is a decline of 6.4 in UMSARS of moderate MSA patients[i].

Comparison of the mean change from baseline in UMSARS scores between the patients in the moderate group and those in the advanced group indicates a statistically significant lower increase in UMSARS score (2 points) in the moderate group vs. the advanced group (14.5 points) ($p = 0.0345$ by Linear Model for Repeated Measures). MRI volumetry data indicates no significant changes from baseline in the combined volume of gray and white matter in the cerebellum and cerebrum. More on the study design at NCT05698017.

In addition to the clinical study, hOMSC300 cells were also shown to be effective in treating a mouse model of MSA. In these preclinical studies, a single injection of either $2.5x10^5$ or $5x10^5$ hOMSC into the cerebrospinal fluid of 30 mice acts as a disease modifier by exerting neuroprotection on dopaminergic neurons and by dampening neuroinflammation.

About Human Oral Mucosa Stem cells (hOMSC)[1]

Cytora's patented and transformative stem cell platform is based on the discovery of a novel and unique stem cell population in the oral mucosa termed human Oral Mucosa Stem Cells (hOMSC). hOMSC are a unique population of stem cells originating from the neural crest. In the oral cavity, they mediate rapid wound healing compared to other tissues, promote full tissue regeneration, without scarring, and their activity is not affected by age. In addition, this remarkable pattern of wound healing is negligibly affected by diabetes, which is notorious for impeding wound healing in other locations of the body, primarily in the foot.

Cytora has shown that hOMSC are easily propagated without losing their unique stem-cell properties – a tiny biopsy of 4x3x2 mm from a healthy donor generates doses for thousands of doses. These cells combine a high therapeutic potency with an excellent safety profile, and do not elicit immune rejection when transplanted in allogeneic recipients, thus enabling the production of an "off the shelf" stem cell treatment platform for human use.

About Multiple System Atrophy

Multiple System Atrophy (MSA) is a rare and progressive neurodegenerative disorder that affects the body's autonomic functions—such as blood pressure regulation, breathing, bladder control, and motor movements. It is characterized by a combination of symptoms similar to those found in Parkinson's disease, such as muscle rigidity, slowed movement, and impaired balance, along with autonomic disturbances. The exact

[1] Arie I, Pal A, et al., 2024. The Lamina Propria of the Oral Mucosa Harbors a Neural Crest-Like Stem Cell Population Resistant to Hyperglycemia Induced by Diabetes Type II, Medical Research Archives, [online] 12(5). https://doi.org/10.18103/mra.v12i5.5181

cause of MSA is unknown, but it involves the accumulation of abnormal proteins in the brain that damage nerve cells. There is currently no cure, and treatment focuses on managing symptoms and maintaining quality of life. In 2024, the global market for MSA therapeutics was valued at approximately US$ 141 million and is projected to reach US$ 213 million by 2033.

About Cytora

Established in 2018, Cytora is a biopharmaceutical company at the forefront of stem cell therapy. Cytora developed a revolutionary technology to produce off-the-shelf (allogeneic) therapeutic doses of human Oral Mucosa Stem Cells to treat challenging diseases, including chronic wounds such as incurable diabetic foot ulcer (DFU) and degenerative diseases such as Parkinson's Disease, Multiple System Atrophy (MSA), and Alzheimer's Disease. The Company successfully completed a Phase 1/2a study for treating DFU and is currently conducting a Phase 1 study for the treatment of MSA. Cytora's technology platform is based on the discoveries of Prof. Sandu Pitaru, Faculty of Medicine, School of Dentistry at the Tel Aviv University in Israel, who is also the scientific founder of the Company. For additional information, please visit www.cytorastem.com.

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[i] Matsushima M. et al. (2021) Multiple system atrophy in Hokkaido, Japan: a prospective registry study of natural history and symptom assessment scales followed for 5 years. BMJ Open. 11(2):e045100. doi: 10.1136/bmjopen-2020-045100.