CYTORA

FOR IMMEDIATE RELEASE

Cytora Reports Successful Results of Phase 1/2a Trial of Stem Cell Treatment for Diabetic Foot Ulcers

Cytora's proprietary oral mucosa stem cells treatment holds potential to be a gamechanger in the field of stem cell therapy

Yokneam, Israel, April 9 - Cytora, a clinical stage company developing unique stem cell treatments based on human Oral Mucosa Stem Cells (hOMSCs), reported today successful results of a Phase 1/2a clinical trial for treating chronic hard to heal diabetic foot ulcers (DFUs) with its leading allogeneic off-the-shelf cell therapy product, hOMSC200. The study results show that hOMSC200 is safe and did not elicit any immune response in recipients. In addition, hOMSC200 was shown to be significantly more effective than the standard of care procedure in treating DFUs.

"Cytora's unique patented technology, based on oral mucosa stem cells, holds a potential to be a gamechanger in the field of stem cell therapy," stated Prof. Sandu Pitaru, Co-Founder and CTO of Cytora. "We are at the forefront of cell therapy, leveraging a proprietary unique stem cell population discovered in the human oral mucosa. Notably, the embryonic origin of this population is a primordial tissue of the developing embryonic brain. These unique stem cells retain in the adult's oral mucosa the properties of neural and other stem cell types, making them effective in targeting chronic multifaceted diseases, such as chronic wounds, and neurodegenerative and autoimmune diseases. Our Phase 1/2a clinical trial has demonstrated that the use of this stem cell population in humans is safe and effective in treating hard to heal diabetic foot ulcers."

"We are extremely pleased and encouraged by the remarkable results we saw in this Phase 1/2a trial," said Yona Geffen, PhD, CEO of Cytora. "Diabetic foot ulcers are a common complication of diabetes and are extremely difficult to treat, leading to significant morbidity. We are targeting the DFU patient population that do not respond to available treatment options. This study enrolled 21 subjects with a mean wound duration of over 2 years, and our results clearly show that not only is hOMCS200 safe for use, with no recorded adverse events or immunological response to the injected cells, but it is also highly effective. The results of this trial put us on solid footing for applying for an IND during the second half of 2025 that will enable starting a large scale Phase 2 trial for treating DFUs during 2026."

The Phase 1/2a trial was a single center, randomized, partially blinded study, comprising two hOMSC200 dose groups (low and high) and one placebo treated group of DFU patients. The study enrolled 21 patients with a mean wound duration of 27 months. Subjects received a single administration of either a high or low dose of

hOMSC200, or a placebo and were followed up for 18 months. All subjects also received standard of wound care treatments. The primary end point was safety, including treatment-related adverse events and immunological rejection reactions towards the injected cells. Secondary end points included partial and complete wound closure rate.

Results show no recorded adverse events, and no humoral or cellular immune response elicited by the injected cells. The proportion of complete wound closure was higher in the hOMSC200-treated patients in comparison to placebo in all populations, with no significant difference between the low and high dose groups. In the intent to treat (ITT) analysis, there was a 53% wound closure rate in the treatment group versus a 33% wound closure rate in the placebo group. In the per protocol group, which included 12 patients who adhered to protocol guidelines, there was a 100% success rate, versus a 20% success rate of wound closure in the placebo control group.

About Human Oral Mucosa Stem cells (hOMSCs)[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). hOMSCs 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 hOMSCs 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 treatments. 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 Diabetic Foot Ulcers
Diabetic foot ulcers (DFUs) are open sores or wounds that occur in individuals with diabetes, due to poor circulation, neuropathy, and impaired wound healing. They can lead to severe infections, gangrene, and even amputation. Approximately 19% to 34% of individuals with diabetes are expected to develop DFU during their lifetime. Treatments include wound care, infection control, offloading pressure, and improving blood sugar control. Advanced treatments include skin grafts, hyperbaric oxygen therapy, and growth factor therapies. Despite all these treatment options, DFUs remain a significant medical challenge, with a healing rate of only 75%, 17% require amputation. In addition, there is a significant increase in mortality rates among patients with DFUs, surpassing that of diabetes alone. There are approximately 1.2M new DFU patients per year in the US alone, with an average treatment cost of $20,000, and severe cases (resulting in amputations) costing > $40K. The global yearly market is estimated at $7.6 Billion.

[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

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 ulcers (DFUs) 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 DFUs 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.

Media contact:
Tsipi Haitovsky
Global Media Liaison
+972-52-598-9892
Tsipihai5@gmail.com