Kadimastem Submits IND Application to the FDA for its Phase IIa Clinical Trial with AstroRx® for the Treatment of ALS

The study will Determine if Repeated Dosing of AstroRx® in Three-month Intervals Achieves a Continuous Delay of the Progression of ALS to Prolong and Improve the Quality of Life of the Patients.

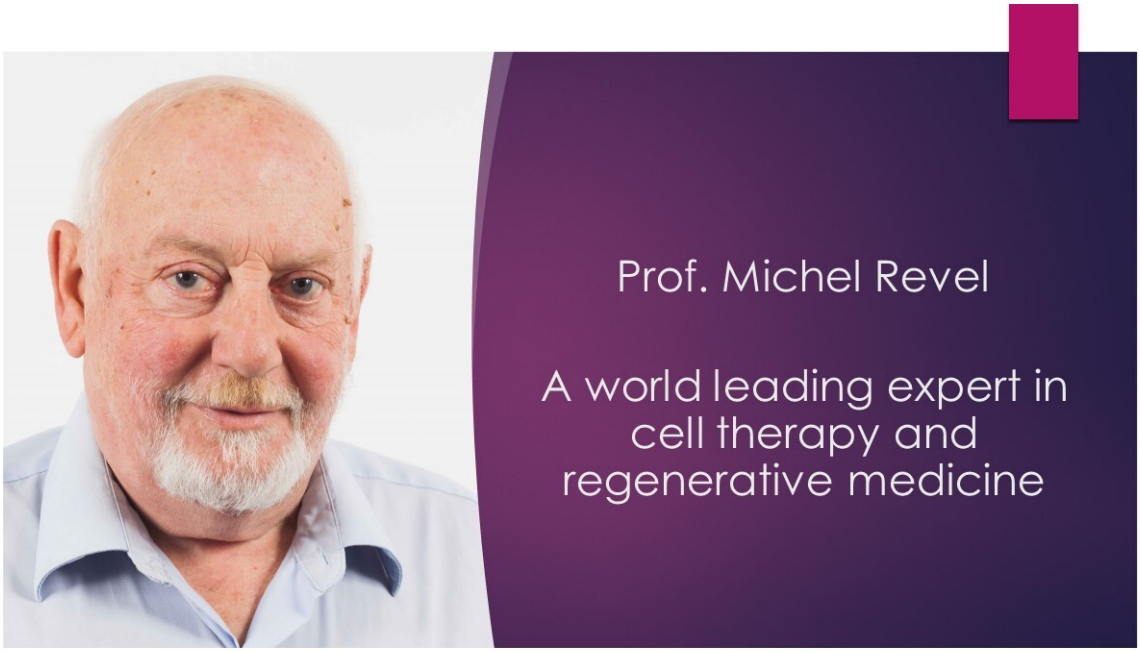
NEWS RELEASE BY **KADIMASTEM LTD.**

Ness Ziona, Israel | February 20, 2023 07:00 AM Eastern Standard Time

Kadimastem Ltd. (TASE: KDST), a well-known biotech company in the field of cellular therapy, which is in the clinical development stages of innovative products for the treatment of ALS and potential cure for diabetes, has submitted an **Investigational New Drug (IND)** application to the U.S. Food and Drug Administration (FDA) for an approval for a multi-site phase IIa clinical trial to test its lead neurological cell therapy product, AstroRx® for the treatment of patients with ALS.

Pending the FDA approval of the IND submission, the planned multi-site phase IIa clinical trial intends to examine for the first time the repeated administration of AstroRx® every 3 months in order to prolong the therapeutic effect observed in the **first in human phase I/IIa clinical trial** conducted by the company in Israel at Ein Kerem Hadassah Hospital from 2018-2020. AstroRx® was injected into the spinal cord fluid using a single standard lumbar puncture procedure, in which they demonstrated a good safety profile and clinically meaningful decline in the disease progression during the first 3-month follow-up period. The results of the clinical trial were published in February of 2023 in the prestigious scientific ***Journal of Translational Medicine***.

AstroRx® contains functional, healthy astrocytes (nervous system supporting cells) derived from human Embryonic Stem Cells (hESC) that aim to protect diseased motor neurons through several mechanisms of action. The goal is to nourish and support the malfunctioning motor neurons in the brain and spinal cord of patients suffering from Amyotrophic Lateral Sclerosis (ALS), in order to slow the progression of the disease, improve quality of life and extend life expectancy for these patients.



Kadimastem Founder and Chief Scientific Officer Professor Michel Revel

Kadimastem Founder and Chief Scientific Officer Professor Michel Revel said, "The submission of an IND to the FDA is a major milestone. It is very exciting to have arrived at this juncture. We eagerly await the approval to start this trial and wanting to help ALS patients as soon as possible."

Kadimastem CEO Asaf Shiloni said, "I'd like to congratulate our scientific team on the extremely important IND submission to the FDA. I would like to thank our VP of R&D Dr. Michal Izrael, our Regulatory Affairs Manager Dr. Vered Morad, our Director of Clinical Affairs Dr. Guy Slutsky, for their special effort and quality submission to the FDA. It is an enormous undertaking which brings great hope for the future. In 2022 we were awarded **multiple patents worldwide**, including from the United States Patent and Trademark Office, Japanese and Israeli patent offices for our cell therapy technology for treating ALS and other neurodegenerative diseases, as well as patents based on our cell therapy for diabetes. In addition, we have been engaging in very high-level discussions with various potential partners to advance both our ALS and diabetes programs."

Kadimastem Executive Chairman of the Board Ronen Twito said, "For the last year, we've reported our plans to submit an IND to the FDA with AstroRx® for the treatment of ALS. The Submission of the IND marks a significant milestone for the company, and subject to the approval of the FDA we hope to commence this very important multi-site trial and to bring this potential life enhancing therapy to the market and to patients as soon as possible. In addition, we are moving forward with our plans to list on the NASDAQ when conditions allow, in order to expose the company to the American markets and the significant analytical capabilities of the major investment banks."

About AstroRx® & ALS

Kadimastem's flagship product, AstroRx®, is a breakthrough technology that is comprised of a unique and large cell population of astrocytes derived from human pluripotent stem cells. The cells are intended to support the survival of motoneurons (the neurons control the motor-capability) in the central nervous system (CNS, brain, and spinal cord). These neurons are damaged in ALS, due to the harsh conditions in the CNS of the ALS patient and the consequential and eventual malfunctioning of

the patient's own astrocytes. This situation hampers and annuls the neuromuscular signaling, which leads to eventual paralysis and death.

In December 2020, Kadimastem announced the results of the ***first of its kind*, Phase I/IIa clinical trial**, in which healthy and functioning astrocyte cells (AstroRx®) were injected into the spinal fluid of 10 ALS patients. Data showed that AstroRx® has the potential to slow the progression of ALS, as indicated by a clinical score called ALSFRS-R. Kadimastem plans to test repeated doses every three months of AstroRx® to achieve a continuous delay of the disease.

Based on data that the company has to date, the company estimates that approximately 3 years after the completion of the upcoming clinical trial and receiving marketing approval, the marketing potential of AstroRx® in ALS patients in the US could reach approximately 0.5 billion dollars annually[1] . In addition, the product would be marketed in additional markets while concomitantly being tested in clinical trials in other neurodegenerative indications in the US.

About Kadimastem

Kadimastem is a clinical stage cell therapy company, developing and manufacturing "off-the-shelf", allogeneic, proprietary cell products based on its technology platform for the expansion and differentiation of Human Embryonic Stem Cells (hESCs) into functional cells. AstroRx®, the company's lead product, is an astrocyte cell therapy in clinical development for the treatment for ALS and in pre-clinical studies for other neurodegenerative indications.

IsletRx is the company's treatment for diabetes. IsletRx is comprised of functional, insulin and glucagon producing and releasing pancreatic islet cells, intended to treat and potentially cure patients with insulin-dependent diabetes.

[1] **https://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/als/conditions/als_amyotrophic_lateral_sclerosis.html**.

https://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/als/conditions/als_amyotrophic_lateral_sclerosis.html. Based on data from the aforementioned source (there are 30,000 ALS patients in the US, as well as 5,000 new cases of ALS that are diagnosed each year), and under the following assumptions: (1) gradual entry into the market after receiving approval for the product; (2) each cellular treatment in the US will cost the payer at least about 25,000 US dollars (based on the benchmark work performed by the company); (3) Each ALS patient in the US will require about 4 cellular treatments from the company in one year, that is, an annual cost of at least about 100,000 US dollars.

Kadimastem was founded by Professor Michel Revel, CSO of the company and Professor Emeritus of Molecular Genetics at the Weizmann Institute of Science. Professor Revel received the Israel Prize for the invention and development of Rebif®, a multiple sclerosis blockbuster drug sold worldwide. Kadimastem is traded on the Tel Aviv Stock Exchange (TASE: KDST).

Forward Looking Statement

This document may include forward-looking information as defined in the Securities Law, 5728 – 1968. Forward-looking information is uncertain and mostly is not under the Company's control and the realization or non-realization of forward-looking information will be affected, among other things, by the risk factors characterizing the Company's activity, as well as developments in the general environment and external factors affecting the Company's activity. The Company's results and achievements in the future may differ materially from any presented herein and the Company makes no undertaking to update or revise such projection or estimate and does not undertake to update this document. This document does not constitute a proposal to purchase the Company's securities or an invitation to receive such offers. Investment in securities in general and in the Company in particular

bears risks. One should consider that past performance does not necessarily indicate performance in the future.

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