# Kadimastem Earns FDA Approval of its IND Application For its US Multi-Site Phase IIa Clinical Trial of AstroRx® to Treat ALS

IND Approval Allows Commencement of the Multi-Site Clinical Trial and Recruitment of Eligible ALS Patients for Repeated Dosing of AstroRx® in Three-Month Intervals

NEWS RELEASE BY **KADIMASTEM LTD.**

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**Kadimastem Ltd.** (TASE: KDST), a clinical stage cell therapy company, developing and manufacturing "off-the-shelf" allogeneic cell products using its platform technology to develop treatments for different neurodegenerative diseases and a potential cure for diabetes, has received FDA clearance to commence a phase IIa clinical trial in the US according to the Investigational New Drug (IND) application that was submitted in February 2023. The trial will test its lead neurological cell therapy product **AstroRx®** in repeated dosing of three-month intervals for the treatment of patients with ALS.

The planned clinical trial follows a **first in human phase I/IIa clinical** trial previously conducted by the company in Israel, in which AstroRx® was injected into the spinal cord fluid using a standard lumbar puncture procedure. In this phase I/IIa clinical trial Kadimastem demonstrated a **good safety profile** and clinically meaningful decline in the disease progression during the first 3-months follow-up period.

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

**Kadimastem CEO Asaf Shiloni said**, "The FDA approval for this multi-site clinical trial is a major achievement for us and is a recognition of our professional, clinical and scientific abilities. I'd like to congratulate our dedicated team on this extremely important landmark, which is an enormous milestone that brings great hope for the future of the ALS patients as well as our supporters and investors."

**Kadimastem Founder and Chief Scientific Officer Professor Michel Revel said**, "The approval of submission of the IND to the FDA is a major achievement and moment of

pride for me in the company that I have founded years ago, with an amazing team. It is very exciting, and we eagerly await to start this trial and wish to help ALS patients as soon as possible."

### 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 (neurons the control the motor-capability) in the central nervous system (CNS, brain and spinal cord). AstroRx® enables the transplantation of healthy astrocytes into the CNS of the ALS patient and an improvement in the protection of the motoneurons.

In December 2020, **Kadimastem announced the results**

**Kadimastem (TASE:KDST) is a clinical stage biotechnology company, with a unique platform for cell therapy that enables the production of off-the-shelf cell-based products for the treatment of unmet medical needs.**

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.

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