

Kadimastem Awarded Patent in Australia for its AstroRx® Technology for the Treatment of ALS and Drug Screening



It's in addition to the company's patents for the product in the US, Europe, Japan and Israel. The patent grant strengthens the company's assets for the planned Phase IIa clinical trial in the U.S.

NEWS RELEASE BY KADIMASTEM LTD.

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Kadimastem Ltd. (TASE: KDST), a clinical stage cell therapy company developing a treatment for ALS, and developing a potential cure for diabetes, has received a patent from the Australian Patent Office for production technology of **AstroRx®** containing healthy functioning astrocytes for the treatment of ALS and drug screening.

This patent accompanies the company's patents for the product in the US, Europe, Japan, and Israel, and is significant to have been granted before the planned phase IIa clinical trial in the US scheduled for the coming year.

The patent protects the manufacturing technology of the company's leading product, AstroRx®, for the use and treatment of ALS (Amyotrophic Lateral Sclerosis). In addition, the patent protects the use of the company's platform cell-based drug screening technology to discover compounds with therapeutic potential.

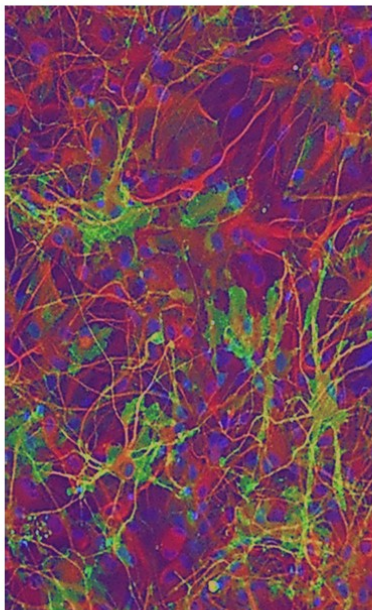


Photo by Kadimastem

AstroRx® contains astrocytes

AstroRx® contains astrocytes, the supporting cells of the central nervous system (brain and spinal cord) whose activity is impaired in many neurological diseases such as ALS. In ALS patients, the ability of astrocytes to maintain a normal survival environment that supports the motor neurons is impaired and as a result there is massive cell loss of the motor neurons, which are responsible for the movement of the voluntary muscles.

The company's assumption is that the injection of healthy, functioning astrocytes into the spinal cord fluid of ALS patients in a standard lumbar puncture procedure is expected to compensate for the dysfunction of the diseased astrocytes and support the survival of the suffering motor neurons, thereby slowing the progression of the disease. Unlike small chemical drugs that usually work with a single mechanism of action, the astrocytes operate with several different mechanisms of action at the same time, each of which individually may protect the motor neurons that are affected by the disease.

Kadimastem completed a clinical trial (Phase I/IIa), in which the cells were injected into the spinal cord fluid using a standard lumbar puncture procedure in 10 ALS patients. The results of the trial demonstrated a high safety profile, as well as a clinically meaningful effect maintained over the first 3 months period after treatment, as measured by the pre vs post slope change of a clinical score known as ALS Functional Rating Score (ALSFRS-R)

Asaf Shiloni, CEO of Kadimastem, commented: "The patent granted in Australia, which joins the patent we received a few months ago in the U.S., continues to strengthen our patent portfolio in the field of treatment for ALS and other neuro-degenerative diseases. This is a testimony and recognition of the innovation of the science developed at Kadimastem and we are working intensively to complete the filing of an IND submission in anticipation to begin clinical trials in the U.S."

Prof. Michel Revel, Kadimastem's Chief Scientist, said: "The ALS program continues to move forward as the company's patent technology continues to strengthen. The company's vision of providing treatment to ALS patients continues to advance, and I am confident that the science developed in the company will greatly help patients in the future."

In Australia there are currently about 2,000 ALS patients, with about 730^[1] ALS patients diagnosed each year.

About Kadimastem

Kadimastem Ltd. 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 based cell therapy in clinical development for the treatment for ALS.

IsletRx is the company's second product in development. IsletRx is comprised of functional, insulin producing, pancreatic islet cells intended to treat and cure patients with insulin-dependent diabetes.

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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[1] **<https://medicalrepublic.com.au/unravelling-the-complexities-of-als/57092>**

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