

BrainStorm certified with GMP approval

08 January 2018 | News

Clinically meaningful changes in functioning is observed in patients receiving NurOwn



BrainStorm Cell Therapeutics Inc, a leading developer of adult stem cell technologies for neurodegenerative diseases.

The company has made announcement that it received Good Manufacturing Practice (GMP) approval from the Israel Ministry of Health (MoH) for its Israeli contract manufacturing facility.

The GMP certificate confirms the company's manufacturing site compliance with Israeli GMPs which are recognized as equivalent with the European Union's GMP.

This approval paves the way for the company's application to the Israel MoH for the treatment of ALS patients in Israel for a fee, under the newly introduced Hospital Exemption regulation.

ALS (amyotrophic lateral sclerosis) is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord.

NurOwn is a novel advanced stem cell therapy now being studied in a multi-site Phase 3 pivotal trial at leading ALS centers.

The company is trying to make it available to patients through innovative regulatory pathways.

The GMP certificate was granted after an inspection of BrainStorm's contract manufacturing facilities.	