HBL Bio-Holding's Portfolio Company Cell Cure Neurosciences Ltd. Receives FDA Authorization to Initiate Phase I/IIa Trial of *OpRegen*® for the Treatment of the Dry Form of Age-Related Macular Degeneration

- **IND cleared for Phase I/IIa dose escalation trial in patients with the dry form of age-related macular degeneration (AMD) with geographic atrophy (GA)**
- **No approved therapy exists for dry-AMD, the leading cause of visual impairment in an aging population**
- ***OpRegen*® will be the first preparation of xeno-free human embryonic stem cell-derived RPE cells evaluated for transplant therapy of dry-AMD**

JERUSALEM, ISRAEL, November 3, 2014 – HBL Hadasit Bio-Holdings Ltd. (TASE: HDST, OTC: HADSY) today announced that the United States Food and Drug Administration (FDA) has cleared an Investigational New Drug (IND) application by Cell Cure Neurosciences (an HBL Hadasit Bio-Holdings portfolio company) to initiate a Phase I/IIa clinical trial of *OpRegen*® in patients with the severe form of age-related macular degeneration (AMD) with geographic atrophy (GA). While treatment options exist for the treatment of the wet form of AMD, it amounts to only about 10% of the disease prevalence. There is currently no FDA-approved therapy for the dry form of the disease occurring in approximately 90% of all patients. *OpRegen*® consists of animal product-free retinal pigment epithelial (RPE) cells with high purity and potency that were derived from human embryonic stem cells (hESCs). Cell Cure intends to transplant *OpRegen*® as a single dose into the subretinal space of patients' eyes in order to test the safety and efficacy of the product in this leading cause of blindness. Patient enrollment is expected to begin in 2014 following approval of the trial by the Israel Ministry of Health.

The clinical trial, "Phase I/IIa Dose Escalation Safety and Efficacy Study of Human Embryonic Stem Cell-Derived Retinal Pigment Epithelium Cells Transplanted Subretinally in Patients with Advanced Dry-Form Age-Related Macular Degeneration with Geographic Atrophy" will evaluate three different dose regimens of *OpRegen*®. The study will be performed at Hadassah Ein Kerem Medical Center in Jerusalem, Israel. Following transplantation, the patients will be followed for 12 months at specified intervals, to evaluate the safety and tolerability of *OpRegen*®. Following the initial 12 month period, patients will continue to be monitored at longer intervals for an additional period of time. A secondary objective of the clinical trial will be to examine the ability of transplanted *OpRegen*® to engraft, survive, and moderate disease progression in the patients. In addition to thorough characterization of visual function, a battery of ophthalmic imaging modalities will be used to quantify structural changes and rate of GA expansion.

"The FDA's acceptance of our IND for the Phase I/II trial of *OpRegen*® is a significant milestone for our company, and in the broader development of therapies based on human embryonic stem cells for the treatment of major diseases, "said Benjamin Reubinoff, MD, PhD, Chief Scientific Officer of Cell Cure and Chairman of Obstetrics and Gynecology and Director of the Hadassah Human Embryonic Stem Cell Research Center at Hadassah Medical Center, Jerusalem, Israel. "We look forward to initiating this first-of-its kind study, and to continuing the clinical development of *OpRegen.*"

“Cell Cure’s Phase I/IIa study of *OpRegen*® has been designed to provide preliminary, objective functional and structural data on the ability of hESC-RPE cell transplantation to slow the progression of geographic atrophy, in addition to safety data” added Prof. Eyal Banin, Head of the Center for Retinal and Macular Degenerations at the Department of Ophthalmology of Hadassah University Medical Center, Jerusalem, Israel who together with Prof. Reubinoff helped develop this novel treatment over the last decade. “We are truly excited that this unique, hESC-based therapy will finally be tested in patients with dry-AMD which severely impacts the quality of life of the elderly, and for which no approved therapy yet exists,” Dr. Banin stated.

About Age-Related Macular Degeneration

Age-related macular degeneration (AMD) is one of the major diseases of aging and is the leading eye disease responsible for visual impairment of older persons in the US, Europe and Australia. AMD affects the macula, which is the part of the retina responsible for sharp, central vision that is important for facial recognition, reading and driving. There are two forms of AMD. The dry form (dry-AMD) advances slowly and painlessly but may progresses to geographic atrophy (GA) in which RPE cells and photoreceptors degenerate and are lost. Once the atrophy involves the fovea (the center of the macula), patients lose their central vision and may develop legal blindness. There are about 1.6 million new cases of dry-AMD in the US annually, and as yet. there is no effective treatment for this condition. The yearly economic loss to the gross domestic product in the United States from dry-AMD has been estimated to be $24.4 billion. The market opportunity for a treatment for GA has been estimated at over $5 billion globally. About 10% of patients with dry-AMD develop wet (or neovascular) AMD, the second main form of this disease, which usually manifests acutely and can lead to severe visual loss in a matter of weeks. Wet-AMD can be treated with currently-marketed VEGF inhibitors such as Lucentis or Eylea. However, such products typically require frequent repeated injections in the eye, and patients often continue to suffer from continued progression of the underlying dry-AMD disease process. Current estimated annual sales of VEGF inhibitors for the treatment of the wet form of AMD are estimated to be about $7 billion worldwide. The root cause of the larger problem of dry-AMD is believed to be the dysfunction of RPE cells. One of the most exciting therapeutic approaches to dry-AMD is the transplantation of healthy, young RPE cells to support and replace the patient’s old degenerating RPE cells, which may prevent progression of the atrophy as well as the development of wet-AMD. Pluripotent stem cells, such as hESCs, can provide an unlimited source for the derivation of such healthy RPE cells for transplantation.

About OpRegen®

Cell Cure's *OpRegen*® consists of RPE cells that are produced using a proprietary process that drives the differentiation of human embryonic stem cells into high purity RPE cells. *OpRegen*® is also “xeno-free," meaning that no animal products were used either in the derivation and expansion of the human embryonic stem cells or in the directed differentiation process. The avoidance of the use of animal products eliminates some safety concerns. *OpRegen*® is formulated as a suspension of RPE cells. Preclinical studies in mice have shown that following a single subretinal injection of *OpRegen*® as a suspension of cells, the cells can rapidly organize into their natural monolayer structure and survive throughout the lifetime of the animal.

OpRegen® will be an "off-the-shelf" allogeneic product provided to retinal surgeons in a final formulation ready for transplantation. Unlike treatments that require multiple, frequent injections into the eye, such as currently-marketed products like Lucentis and Eylea for wet-AMD, it is expected that *OpRegen*® would be administered in a single procedure.

About Cell Cure Neurosciences Ltd.

Cell Cure Neurosciences Ltd. was established in 2005 as a subsidiary of ES Cell International Pte. Ltd. (ESI), now a subsidiary of BioTime, Inc. (NYSE MKT: BTX). Cell Cure's second largest shareholder is HBL- Hadasit Bio-Holdings, (TASE: HDST, OTC: HADSY). Cell Cure is located in Jerusalem, Israel on the campus of Hadassah Medical Center. Cell Cure's mission is to become a leading supplier of human cell-based therapies for the treatment of retinal and neural degenerative diseases. Its technology platform is based on the manufacture of diverse cell products sourced from clinical-grade (GMP-compatible) human embryonic stem cells. Its current focus is the development of retinal pigment epithelial (RPE) cells for the treatment of age-related macular degeneration. Cell Cure's major shareholders include BioTime, Inc., HBL Hadasit Bio-Holdings Ltd., Teva Pharmaceuticals Industries Ltd. (NYSE: TEVA), and Asterias Biotherapeutics (OTCBB: ASTY). Additional information about Cell Cure can be found on the web at www.cellcureneurosciences.com. A video of a presentation by Cell Cure's CEO Dr. Charles Irving is available on BioTime's web site.

Forward-Looking Statements

Statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for HBL Hadasit Bio-Holdings Ltd and its portfolio companies along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the business of HBL Hadasit Bio-Holdings Ltd and its portfolio companies, particularly those mentioned in the cautionary statements found in HBL Hadasit Bio-Holdings Ltd's security filings. HBL Hadasit Bio-Holdings Ltd disclaims any intent or obligation to update these forward-looking statements.