# Medgenics Cleared to Initiate Phase IIa Anemia Study of EPODURE Biopump in Dialysis Patients in Israel

MISGAV, Israel and SAN FRANCISCO--(BUSINESS WIRE [1])--Medgenics, Inc., the developer of a novel technology for the sustained production and delivery of therapeutic proteins in patients using their own tissue, today announced receipt of clearance from the Israeli Ministry of Health to initiate a Phase IIa clinical study evaluating the safety and efficacy of sustained erythropoietin ("EPO") therapy produced and delivered by the Companys EPODURE™ Biopumps™. The study will assess EPODUREs ability to replace months of routine EPO injections for the treatment of anemia in patients with end-stage renal disease ("ESRD" or "kidney failure") who are on dialysis.
EPODURE is an autologous dermal Biopump, a small tissue implant made from the patients own dermal (skin) tissue, processed to enable it to continuously produce EPO. EPODURE Biopumps are subsequently implanted subcutaneously into the patient to provide continuous delivery of EPO.

"Our EPODURE Biopump technology offers potential advantage over current therapy because it enables patients to continuously produce and deliver their own EPO within the normal physiological range. Sustained delivery of EPO is expected to help keep hemoglobin within the target range to reduce the risks of hemoglobin variability, while avoiding the possible risks posed by EPO concentrations many times the normal physiological range, as observed with EPO administrations. EPODURE could potentially be a safer anemia management tool. Additionally, the cost benefits for the management of anemia could be highly significant," said Andrew L. Pearlman, Ph.D., President and Chief Executive Officer of Medgenics.

This open-label Phase IIa study will enroll up to 20 dialysis patients with anemia due to ESRD who have been receiving routine EPO injections three times per week. Each patient will receive an individually targeted initial dose of EPODURE Biopumps designed to produce levels of EPO that would replace the routine EPO injections over a period of 4-12 months. The EPODURE dose may be adjusted if needed by adding or removing Biopumps, emulating the standard care, dose adjustments, currently made with injected EPO. The studys objective is to maintain hemoglobin levels within the desired therapeutic range without the need for EPO injections. The study will be conducted at the Tel Aviv Sourasky Medical Center by principal investigator Doron Schwartz, M.D., Head of the Centers Nephrology Department. The Ministry of Health has approved the Companys commencement of the recruitment and treatment of patients, subject to a follow-up safety review on June 19, 2012, similar to the protocol followed in the Phase I/II pre-dialysis study.

Dr. Pearlman continued, "We are pleased to have been cleared to initiate this Phase IIa study in dialysis patients, which we expect will build on the positive clinical results from our earlier Phase I/II study of EPODURE to treat pre-dialysis patients

with chronic kidney disease. This is the first clinical study that will permit adjustment of the EPODURE dose based on patients needs as is currently done in standard EPO treatment, and will be standard in future EPODURE use. This represents a significant change from the fixed-dose study we previously conducted in pre-dialysis patients.

"This is the second EPODURE study to be approved by Israels regulatory agency and will be conducted at the same medical center, with the same principal investigator as our previous study. We believe this indicates growing confidence with the EPODURE Biopump in the treatment of anemia, and supports our clinical strategy. As ESRD patients represent the largest market segment in renal anemia, we look forward to initiating our first clinical trial in dialysis patients and are confident that the Phase IIa study results will affirm the positive data from our study of EPODURE in pre-dialysis patients demonstrated that a single administration can raise and maintain hemoglobin levels for many months without any injections of EPO or other erythropoietin stimulating agents ("ESAs"). In parallel with this new Phase IIa trial in Israel, we are on track to file an Investigational New Drug application for a larger Phase IIb trial in the U.S. and, subject to U.S. Food and Drug Administration approval, look forward to obtaining clearance for that trial later this year," concluded Dr. Pearlman.

About Anemia
Anemia is a common complication of renal failure resulting primarily from insufficient production of the hormone EPO by the damaged kidneys, which leads to a decrease in production of red blood cells. Treatment with EPO typically involves intravenous or subcutaneous administration by injection at regular intervals followed by frequent laboratory tests to monitor hemoglobin concentration. Due to the short half-life of the protein, it is usually administered at doses that result in super physiological levels, which then decline into a more physiologic range. This variability in levels, and in particular the peak levels, has been hypothesized to potentially increase the risk of adverse cardiovascular effects and may make maintenance of steady hemoglobin levels more challenging. The need for frequent injections and laboratory tests, medication compliance and lifestyle adjustment are potential barriers to achieving the desired hemoglobin goal. These barriers, together with the high costs of the currently available recombinant EPO products, provide an incentive to improve care with a sustained therapy approach.

About Medgenics
Medgenics is developing and commercializing Biopump™, a proprietary tissue-based platform technology for the sustained production and delivery of therapeutic proteins using the patient's own skin biopsy for the treatment of a range of chronic diseases including anemia, hepatitis C and hemophilia. Medgenics believes this approach has multiple benefits compared with current treatments, which include regular and costly injections of therapeutic proteins.

Medgenics has three long-acting protein therapy products in development based on this technology:

- EPODURE™ (now completing a Phase I/II dose-ranging trial) to produce and deliver erythropoietin for many months from a single administration, has demonstrated elevation and stabilization of hemoglobin levels in anemic patients for six to more than 36 months;
- INFRADURE™ (planning to commence a Phase I/II trial in Israel in 1H12 in hepatitis C) to produce a sustained therapeutic dose of interferon-alpha for use in the treatment of hepatitis;
- HEMODURE™ is a sustained Factor VIII therapy for the prophylactic treatment of hemophilia, now in development.

Medgenics intends to develop its innovative products and bring them to market via strategic partnerships with major pharmaceutical and/or medical device companies.

In addition to treatments for anemia, hepatitis and hemophilia, Medgenics plans to develop and/or out-license a pipeline of future Biopump products targeting the large and rapidly growing global protein therapy market, which is forecast to reach $132 billion in 2013. Other potential applications for Biopumps include multiple sclerosis, arthritis, pediatric growth hormone deficiency, obesity and diabetes.

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