Regenerative Medicine Could Hold Next Steps in Treating Foot and Leg Ulcers

Newswise — These are exciting times for regenerative medicine. Unlike conventional medicines, the regenerative approach can potentially work to restore the lost functionality of tissues or organs—the major reason for intensive focus on research and development in the field. The global market is projected to reach $67.6 billion by 2020, up from $16.4 billion in 2013, according to a report released in summer 2014 by market intelligence company Allied Market Research.

“Regen med” is divided into discrete areas: small molecules and biologics, gene therapy and cell therapy. One of today’s most interesting applications of cell therapy involves the treatment of diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs), both of which have historically suffered from a lack of effective treatments.

Diabetic foot ulcers are open sores or wounds that occur in about 15 percent of patients with diabetes, according to the American Podiatric Medical Association (APMA). Of those who develop DFUs, about six percent will be hospitalized due to infection or other ulcer-related complications. Foot ulcerations, the APMA reports, precede 85 percent of diabetes-related amputations. Novel, effective methods of tackling DFUs are greatly needed. But according to a recent review in the journal Advances in Therapy, the development of new treatments in this area has stalled for the past two decades. According to lead author Aristidis Veves, MD, the number of cases of DFUs and amputations has remained the same over the past 10 to 15 years. One issue that remains challenging is developing effective wound dressings for DFUs. Many types exist, says Veves, but there is not much evidence to show that any one is better than any other.

Meanwhile, venous leg ulcers (VLUs) are shallow wounds that occur when the leg veins don’t return blood back toward the heart the way they should, a condition called venous insufficiency. According to WebMD, these ulcers usually form on the sides of the lower leg, above the ankle and below the calf. VLUs are slow to heal and often recur if steps aren’t taken to prevent them. A newsworthy setback in the potential treatment of VLUs occurred in October 2014, when medical technology company Smith & Nephew announced that its product HP802-247—a spray-on skin treatment consisting of living cells—had failed in a late-stage clinical trial involving VLU patients. The spray is targeted at people with VLUs whose skin will not heal with conventional treatments, such as compression dressings, and for whom the only alternative option could be skin graft.

But what if DFUs could best be treated and closed, not by surface dressings, but by injecting the human body’s own wound-healing and regenerative components directly into the wound itself? This novel therapeutic approach has been pursued—with extremely encouraging results—by Macrocure Ltd., a regenerative medicine company based in Israel. Its lead product candidate, CureXcell™, is an advanced wound care therapy that has been used to effectively treat more than 5,000 patients to date in commercial or clinical study settings in Israel. It has been approved as a medical device in Israel, and Macrocure is currently conducting two pivotal, Phase 3, double-blind clinical trials in patients with DFUs and VLUs. Results are anticipated from the DFU trial and interim data from the VLU trial in the second half of 2015.

CureXcell is an injectable suspension of living white blood cells, including macrophages, neutrophils and lymphocytes, that are crucial to initiating, promoting and completing the process of cellular regeneration and wound healing. Macrocure activates the white blood cells via its proprietary hypo-osmotic shock cell activation technology, a process that changes the concentration and pH of the suspension surrounding the cells. Once activated, these cells undergo a change in gene expression that results in an increase in the cells’ secretion of numerous growth factors and other biochemical factors. This improves the healing environment in the wound bed and stimulates wound closure better than any dressing that does not come into contact with the impaired cells beneath the surface.

The company sources white blood cells from fully screened, healthy, volunteer blood donors age 18 to 40, through established relationships with blood banks, including the American Red Cross. One unit of whole blood from Macrocure’s blood bank partners is sufficient to produce enough CureXcell for 30 injection applications for average-sized wounds. CureXcell is easy to administer and ready to use. A physician draws CureXcell from its sterile package using a standard syringe for injection into a patient’s wound. And as a major boon to patients, the therapy involves only one injection per month.

DFUs and VLUs are expensive problems that can seriously affect the quality of life of diabetes patients. Products such as CureXcell, harnessing the power of regenerative medicine, might offer physicians and their patients a new standard of advanced wound care that is superior to existing approaches.