South Florida Hospital News and Healthcare Report
THE REGION'S MONTHLY NEWSPAPER FOR HEALTHCARE PROFESSIONALS & PHYSICIANS

MediWound Announces Last Patient Out in EscharEx U.S. Phase 2 Trial for the Debridement of Chronic Wounds

Primary Endpoint Met with Highly Statistically Significant Results

Final Data Readout Expected in Second Quarter of 2022

YAVNE, Israel, March 21, 2022 – MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced that the last patient in its U.S. Phase 2 clinical study of EscharEx® for the debridement of

venous leg ulcers (VLUs) has completed the study treatment visits as well as the required follow up.

As previously announced on January 24, 2022, the study met its primary endpoint with high degree of statistical significance. Patients treated with EscharEx demonstrated a higher incidence of complete debridement during the 14-day measurement period within up to 8 applications compared to patients treated with gel vehicle (EscharEx: 63% (29/46) vs. gel vehicle: 30% (13/43), p-value=0.004). Final data set readout, including secondary and exploratory endpoints as well as additional safety measurements, which will allow further evaluation of clinical benefits, is expected in the second quarter of 2022.

“We are pleased to announce the completion of patient treatment and follow-up in this Phase 2 study, which represents another important milestone for MediWound and our EscharEx clinical program,” said Sharon Malka, Chief Executive Officer of MediWound. “Given the recent primary efficacy data from this study and from prior studies, which showed complete debridement in a matter of days, we believe EschaEx has the potential to become a best-in-class debridement option for millions of patients suffering from hard-to-heal wounds and is well-positioned to be meaningful part of chronic wound debridement market. We look forward to reviewing the full data set in the coming months with the goal of advancing this exciting program into pivotal Phase 3 clinical trials. We are very grateful to the clinical investigators, trial participants and their families for their time and commitment.”

Study Design

The study is a multicenter, prospective, randomized, placebo-controlled, adaptive design study, evaluating the safety and efficacy of EscharEx in debridement of VLUs compared to gel vehicle (placebo control) and non-surgical standard-of-care of either enzymatic or autolytic debridement. The study randomized 120 patients, at approximately 20 clinical sites, of which 119 patients were treated by either EscharEx (n=46), a gel vehicle (n=43), or a non-surgical standard-of-care consisting of either enzymatic or autolytic debridement (n=30). The primary endpoint was incidence of complete debridement (non-viable tissue removal), clinically assessed, during the assessment period (up to 8 treatment applications within 14 days), compared to gel vehicle placebo control. Secondary and exploratory endpoints assess time to achieve complete

debridement, reduction of pain, reduction of wound area, granulation tissue and quality of life, enabling evaluation of clinical benefits compared to both gel vehicle and non-surgical standard-of-care. Incidence and time to achieve wound closure will be assessed as safety measurements.

For more information regarding this study, please visit www.clinicaltrials.gov.

About EscharEx

EscharEx is a bioactive therapy for debridement of chronic and other hard-to-heal wounds in advanced stages of clinical development. Designed for the outpatient setting, EscharEx is an easy-to-use concentrate of proteolytic enzymes enriched in bromelain for topical daily applications.

In two completed Phase 2 trials, EscharEx was well-tolerated and demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds with only few daily applications. EscharEx's mechanism of action is mediated by the proteolytic enzymes that cleave and remove the necrotic tissue and prepare the wound bed for healing. EscharEx is an investigational product and currently in a U.S. Phase 2 adaptive design study.

As part of its broader EscharEx development program, MediWound is also conducting a Phase 2 open-label, single arm study being conducted at three U.S. clinical sites. The study is designed to evaluate the clinical performance, safety, and pharmacology effect of EscharEx in the debridement of lower leg ulcers (VLUs and diabetic foot ulcers) in up to fifteen patients.

About MediWound Ltd.

MediWound is a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, bio-therapeutic solutions for tissue repair and regeneration. Our strategy leverages our enzymatic technology platform, focused on next-generation bioactive therapies for burn care, wound care, and tissue repair.

NexoBrid, our commercial orphan biological product for non-surgical eschar removal of deep-partial and full-thickness thermal burns, is a bromelain-based biological product containing a sterile mixture of proteolytic enzymes that selectively removes burn eschar within four hours without harming surrounding

viable tissue. NexoBrid is currently marketed in the European Union and other international markets and is at registration-stage in the U.S. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx, our next-generation bioactive topical therapeutic under development in the U.S. for debridement of chronic and hard to heal wounds. In two Phase 2 studies, EscharEx was well-tolerated and has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a few daily applications.

MW005, our topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development.

Committed to innovation, we are dedicated to improving quality of care and patient lives. For more information, please visit www.mediwound.com.

- Webinars
- Contact