MediWound Announces Positive Topline Results From Its U.S. Phase 2 Trial of EscharEx for Debridement of Chronic Wounds

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Primary Endpoint Met with Highly Statistically Significant Results
No Observed Safety Issues
Final Data Readout Expected in Second Quarter of 2022

YAVNE, Israel, Jan. 24, 2022 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced positive topline results from its U.S. Phase 2 clinical study of EscharEx® for the debridement of venous leg ulcers (VLUs). The study met its primary endpoint, demonstrating that patients treated with EscharEx had a statistically significant higher incidence of complete debridement compared to the gel vehicle, with a p-value of 0.004.

The study randomized 120 patients, 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 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). After adjusting for pre-specified covariates ascribed to patient baseline characteristics, wound size and age, regions, and sites, EscharEx efficacy superiority remained statistically significant compared to gel vehicle. Incidence of complete debridement of the non-surgical standard-of-care arm, during the same 14-day measurement period, was 13% (4/30).

In addition, the Independent Data Monitoring Committee reviewed the data of all patients treated and no safety concerns were identified in the study population. EscharEx was well-tolerated and overall safety was comparable between the arms. No differences were found in reported adverse events and no serious adverse event was related to study treatment. Patient baseline characteristics were comparable across all study arms.

"We are excited to report these robust topline results from our U.S. Phase 2 clinical study, which corroborate the results of our prior Phase 2 study. The primary endpoint efficacy data are highly encouraging and further reinforce our belief that EscharEx has the potential to become a best-in-class non-surgical debridement option for the millions of patients suffering from chronic wounds," said Sharon Malka, Chief Executive Officer of MediWound. "Chronic wound care is a billion-dollar market opportunity, and we believe EscharEx is well-positioned to potentially be a meaningful part of that 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."

Patient follow-up is ongoing and additional data, 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. MediWound currently expects to request an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (the "FDA") in the second half of 2022, to discuss program results and the potential Phase 3 pivotal plan for EscharEx.

Dr. Robert Snyder, Chief Medical Director of the EscharEx program added, "I continue to be impressed by the clinical data generated by the EscharEx trials. There is a great unmet medical need to effectively debride chronic wounds in a non-surgical and prompt manner, as debriding the wound is a critical first step for consequent wound management. I believe EscharEx holds great potential to be a significant and welcome addition to our treatment armamentarium for chronic wounds. We thank our partners, the investigative staff, and especially the patients and families for their commitment and perseverance in completing the study in the face of all the challenges posed by the pandemic."

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 enrolled 120 patients, with 119 treated, at approximately 20 clinical sites, primarily in the United States. Study participants were randomized to either EscharEx, gel vehicle placebo control, or non-surgical standard-of-care, at a ratio of 3:3:2, with a three-month follow-up. 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 (A Study to Evaluate the Safety and the Efficacy of EscharEx (EX-02 Formulation) in Debridement of Venous Leg Ulcers - Full Text View - 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.

Cautionary Note Regarding Forward-Looking Statements

MediWound cautions you that all statements other than statements of historical fact included in this press release that address activities, events, or developments that we expect, believe, or anticipate will or may occur in the future are forward-looking statements. Although we believe that we have a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting us and are subject to risks, assumptions, uncertainties, and factors, all of which are difficult to predict and many of which are beyond our control. Actual results may differ materially from those expressed or implied by the forward-looking statements in this press release. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "continues," "believe," "guidance," "outlook," "target," "future," "potential," "goals" and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "could," "may," or similar expressions .

Specifically, this press release contains forward-looking statements concerning the anticipated progress, development, study design, expected data timing, objectives anticipated timelines, expectations and commercial potential of our products and product candidates, including EscharEx. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the uncertain, lengthy and expensive nature of the product development process; the timing and conduct of our studies of our products and product candidates, including the timing, progress and results of current and future clinical studies, and our research and development programs; the approval of regulatory submission by the European Medicines Agency or by any other regulatory authority, our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets; the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of our products and products; our expectations regarding future growth, including our ability to develop new products; risks related to our contracts with BARDA; market acceptance of our products and product candidates; our ability to maintain adequate protection of our intellectual property; competition risks; the need for additional financing; the impact of government laws and regulations and the impact of the COVID-19 pandemic. For example, we are unable to predict how the pandemic will affect the overall healthcare infrastructure, including the ability to recruit patients, the ability to conduct the studies in medical sites and the pace with which governmental agencies, such as the FDA, will review and approve regulatory submissions. Additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation efforts also may impact our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of our products and product candidates in the future.

These and other significant factors are discussed in greater detail in MediWound's annual report on Form 20-F for the year ended December 31, 2020, filed with the Securities and Exchange Commission ("SEC") on February 25, 2021, Quarterly Reports on Form 6-K and other filings with the SEC from time-to-time. These forward-looking statements reflect MediWound's current views as of the date hereof and MediWound undertakes, and specifically disclaims, any obligation to update any of these forward-looking statements to reflect a change in their respective views or events or circumstances that occur after the date of this release except as required by law.

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