MediWound Announces Publication of the EscharEx® Phase II ChronEx Study Results for Venous Leg Ulcers

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Research Published in THE LANCET's eClinicalMedicine

EscharEx® Outperforms Non-Surgical Standard of Care in Debridement and Promotion of Healthy Granulation Tissue

YAVNE, Israel, July 29, 2024 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair, today announces the peer-reviewed publication on the Phase II ChronEx study assessing the safety and efficacy of EscharEx for the treatment of Venous Leg Ulcers (VLU) in the prestigious eClinicalMedicine, a journal under THE LANCET Discovery Science umbrella. The publication, titled "*Once daily Bromelain-based enzymatic debridement of venous leg ulcers versus gel vehicle (placebo) and non-surgical standard of care: a three-arm multicenter, double-blinded, randomized controlled study*", reports the results of the study.

"The publication in eClinicalMedicine highlights the importance of a safe and effective non-surgical treatment for debridement of chronic wounds, particularly venous leg ulcers (VLUs). Removing non-viable tissue and promoting well-vascularized granulation tissue are essential steps in wound bed preparation, which is crucial for successful wound healing," stated Dr. John C. Lantis, Chief of Surgery at Mount Sinai West Hospital and principal investigator in the ChronEx study. "The significant superiority of EscharEx over the current non-surgical standard of care in achieving optimal wound bed preparation could dramatically enhance healing outcomes and provide a viable alternative to surgical debridement. This will be a primary focus of the upcoming EscharEx Phase III trial in treating VLUs."

The Phase II ChronEx study was conducted across 20 medical centers and clinics in the United States, Europe and Israel. Patients were randomized in a 3:3:2 ratio to receive daily treatment with EscharEx, a Gel Vehicle (placebo), or non-surgical standard of care (NSSOC), which included SANTYL®, hydrogels, medical grade honey, and non-active dressings. Treatment lasted for up to two weeks (with a maximum of eight daily applications) or until complete debridement was achieved. Following treatment, patients were monitored weekly for an additional 12 weeks.

Key study outcomes include:

- A total of 119 patients were randomized and treated: 46 in the EscharEx arm, 43 in the placebo arm, and 30 in the NSSOC arm.
- Baseline characteristics of patients and wounds were comparable across all study arms.
- The study met its primary endpoint: the incidence of complete debridement during the two-week daily treatment was 63.0% for EscharEx compared to 30.2% for placebo (P = 0.004). The incidence of complete debridement for NSSOC during the daily treatment period was 13.3% (P < 0.001).
- The median time to complete debridement was 9 days for EscharEx vs. 63 days for placebo (P = 0.004) and 59 days for NSSOC (P = 0.016).
- The incidence of complete cover of the wound bed with healthy granulation tissue during the daily treatment period, was 50.0% for EscharEx compared to 25.6% for placebo (P = 0.01) and 10.0% for NSSOC (P < 0.001).
- Changes in patient-reported pain, wound size, or wound quality of life (QoL) were comparable between the three treatment arms.
- The safety profile of EscharEx was comparable to both NSSOC and the placebo.

About EscharEx

EscharEx® is a bioactive, multimodal debridement therapy for the treatment of chronic and other hard-to-heal wounds, currently in the advanced stages of clinical development. It is a concentrate of proteolytic enzymes enriched with bromelain for topical, easy to use daily applications. In several Phase II trials, EscharEx was shown to be safe and well-tolerated. It demonstrated efficacy in debridement, the promotion of granulation tissue, and the reduction of bioburden and biofilm in various hard-to-heal wounds, effectively preparing the wound bed for healing. MediWound is set to initiate a Phase III study for Venous Leg Ulcers in the second half of 2024, and a Phase II/III study targeting Diabetic Foot Ulcers in the second half of 2025.

About MediWound

MediWound Ltd. (Nasdaq: MDWD) is the global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. The Company specializes in the development, production and commercialization of rapid and effective biologics that improve existing standards of care and patient experiences, while reducing costs and unnecessary surgeries.

MediWound's first drug, NexoBrid ®, is an FDA and EMA-approved orphan biologic for eschar removal in deep partial-thickness and/or full-thickness thermal burns, which can significantly reduce surgical interventions. Utilizing the same core biotherapeutic enzymatic platform technology, MediWound has developed a strong R&D pipeline, including the company's lead drug under development, EscharEx ®. EscharEx is a Phase III-ready biologic for the debridement of chronic wounds, offering significant potential advantages over the dominant $360+ million product and an opportunity to expand the market.

For more information visit www.mediwound.com and follow the Company on LinkedIn.

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 FDA, 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; 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 current global macroeconomic climate on 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, 2023, filed with the Securities and Exchange Commission ("SEC") on March 21, 2024 and 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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