MediWound Announces Publication of Phase II EscharEx® Data Demonstrating Superiority Over Collagenase in Venous Leg Ulcers

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Post hoc analysis published in the peer-reviewed journal Wounds highlights EscharEx®'s superior clinical performance and comparable safety profile to SANTYL®

YAVNE, Israel, May 13, 2025 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a global leader in next-generation enzymatic therapeutics for tissue repair, today announced the publication of a peer-reviewed post hoc analysis in *Wounds*. The analysis is based on data from the Company's Phase II ChronEx clinical trial in patients with venous leg ulcers (VLUs) evaluating the efficacy and safety of EscharEx® compared with collagenase ointment (SANTYL®), the only FDA-cleared enzymatic debridement agent commercially available for the treatment of dermal ulcers.

The article, titled *"Bromelain-Based Debridement Versus Collagenase Ointment Debridement of Venous Leg Ulcers: Post Hoc Analysis of the ChronEx Trial,"* appears in the April 2025 edition of *Wounds* (Index 2025;37(4):166–173) and compares outcomes in a subgroup of patients from the non-surgical standard of care arm treated with SANTYL (n=8) to those treated with EscharEx (n=46).

"These new findings are consistent with my prior experience using EscharEx in clinical trials and SANTYL in clinical practice," said Dr. Cyaandi Dove, DPM, of the University of Texas Health Science Center at San Antonio and co-author of the publication. "Compared to SANTYL, EscharEx achieved faster and more effective debridement and promoted healthier granulation tissue, both key to optimal wound bed preparation. EscharEx's enzymatic formulation targets a wider range of non-viable and necrotic tissue, which may account for the favorable clinical outcomes observed."

Key findings from the post hoc analysis include:

- **Debridement Efficacy:**
  - Complete debridement at 2 weeks was achieved in 63% of EscharEx-treated patients, compared to 0% in the SANTYL group (p = 0.001).
  - Median time to debridement was 9 days for EscharEx vs. not achieved for SANTYL (p = 0.023).
- **Wound Bed Preparation (WBP):**
  - WBP—defined as complete debridement and complete granulation—was achieved by 50% of EscharEx patients ir 2 weeks vs. 0% with SANTYL (p = 0.015).
  - Over the entire study period (12 weeks), 78% of EscharEx patients achieved WBP vs. 38% with SANTYL (p = 0.03).
  - Median time to WBP: 11 days for EscharEx; not achieved for SANTYL (p = 0.014).
- **Wound Closure:**
  - Closure was achieved in 33% of EscharEx patients vs. 25% with SANTYL (not statistically significant).
  - Among those who closed, the mean time to closure was 48 days for EscharEx vs. 76 days with SANTYL (p = 0.05).
- **Safety and Tolerability:**
  - Adverse event rates and applicational pain were similar between groups.
  - Deep wound infection, assessed using recognized clinical criteria, occurred in 11% of EscharEx patients compared to 38% in the SANTYL group.

About EscharEx®

EscharEx® is a bromelain-based, bioactive enzymatic therapy in advanced clinical development for the debridement of chronic and hard-to-heal wounds. Designed for topical, once-daily application, EscharEx has demonstrated a favorable safety profile and effective wound bed preparation in multiple Phase II trials. The therapy has shown the ability to remove non-viable tissue, promote granulation tissue, and reduce bioburden and biofilm. A global Phase III study in venous leg ulcers (VLUs) is currently underway, with a clinical study in diabetic foot ulcers (DFUs) in preparation. EscharEx has shown clinical advantages over the leading enzymatic debridement product and targets a substantial global market opportunity.

About MediWound Ltd.

MediWound Ltd. (Nasdaq: MDWD) is a global biotechnology company focused on developing and commercializing enzymatic therapies for non-surgical tissue repair. The company's FDA-approved biologic, NexoBrid ®, is indicated for the enzymatic removal of eschar in thermal burns and is marketed in the U.S., European Union, Japan, and other international markets. MediWound is also advancing EscharEx®, a late-stage investigational therapy for the debridement of chronic wounds. EscharEx has demonstrated clinical advantages over the leading enzymatic debridement product and targets a substantial global market opportunity.

For more information, visit www.mediwound.com and follow us 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, 2024, filed with the Securities and Exchange Commission ("SEC") on March 19, 2025 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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