MediWound Initiates the VALUE Global Phase III Pivotal Trial of EscharEx® for Treatment of Venous Leg Ulcers

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Phase III trial to assess the efficacy and safety of EscharEx® for debridement and facilitation of active wound closure

Interim analysis planned after 65% of patients complete treatment, expected in mid-2026

Strategic research collaborations with Solventum, Mölnlycke, and MIMEDX

YAVNE, Israel, Feb. 12, 2025 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a global leader in next-generation enzymatic therapeutics for tissue repair, today announced the initiation of VALUE, a global, pivotal Phase III trial evaluating EscharEx® for the treatment of venous leg ulcers (VLUs).

"We are proud to initiate the VALUE study, the most comprehensive VLU trial in over a decade," said Ofer Gonen, Chief Executive Officer of MediWound. "With no new FDA-approved drugs in this category since 1965, EscharEx has the potential to redefine the standard of care for chronic wound debridement. EscharEx has already demonstrated its ability to effectively and rapidly debride chronic wounds in multiple Phase II trials, surpassing the current $375+ million market leader in wound debridement, SANTYL®. We are confident that EscharEx will provide meaningful benefits to patients, healthcare providers, and payors alike."

The VALUE study is a global, multicenter, prospective, randomized, double-blind, placebo-controlled trial with an adaptive design, that will be conducted across 40 sites in the U.S. and Europe. Its primary objective is to evaluate the efficacy and safety of EscharEx in achieving effective debridement and preparing the wound bed for healing in VLUs. The study will enroll 216 patients, randomized 1:1 to receive either EscharEx or placebo. Patients will undergo up to eight daily applications over two weeks, followed by ten weeks of standardized wound management. Patients achieving wound bed preparation—defined as complete debridement and full coverage with granulation tissue—will receive a cellular/tissue-based product (CTP) or an autograft. Those achieving complete wound closure will be monitored for an additional 12 weeks.

The study co-primary endpoints are the incidence of complete debridement and the incidence of complete wound closure. Secondary endpoints include the incidence of complete granulation tissue, time to debridement, time to complete wound closure, and changes in wound area. Safety and tolerability of EscharEx will be assessed throughout the trial. An interim sample size assessment will occur after 65% of patients complete treatments, enabling adaptive adjustments as needed. This interim analysis is expected in mid-2026.

To support the trial, MediWound has established strategic research collaborations with Solventum, Mölnlycke, and MIMEDX. These industry leaders will provide advanced products to ensure consistent wound management across all study sites and optimize patient outcomes.

In addition to the VALUE study, MediWound plans to initiate a randomized, head-to-head Phase II study in 2025, comparing EscharEx to collagenase in VLU patients. This Phase II trial is designed to support the U.S. Biologics License Application (BLA) submission for EscharEx and strengthen MediWound's commercialization strategy. Furthermore, the company is advancing preparations for an adaptive design Phase II/III clinical trial targeting diabetic foot ulcers (DFUs), which is expected to begin in 2026.

About Venous Leg Ulcers[1]

Venous leg ulcers (VLUs) affect approximately 2% of individuals aged 65 and older, with over 1.5 million new cases reported annually in the U.S. These ulcers typically develop on the lower extremities due to chronic venous insufficiency. VLUs are characterized by large, shallow wounds that can cause severe pain, infection, and disability, highlighting the urgent need for effective treatment options. Debridement, a critical first step in managing these wounds, is performed in 68% of cases and is commonly achieved through enzymatic methods like SANTYL®, autolytic debridement, or sharp debridement.

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, designed for topical and easy-to-use daily applications. In three previous 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. EscharEx is currently being investigated in a global Phase III study for the treatment of venous leg ulcers (VLUs). Preparations are underway for a Phase II/III study targeting diabetic foot

ulcers (DFUs).

About MediWound

MediWound Ltd. (Nasdaq: MDWD) is a global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. The Company specializes in the development, production and commercialization of innovative biologics that enhance existing standards of care and improve patient experiences while reducing healthcare 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, significantly reducing the need for surgical interventions. Leveraging its proprietary enzymatic technology, MediWound is advancing EscharEx®, a promising candidate currently in Phase III development for the debridement of chronic wounds. Phase II clinical trials have shown EscharEx has distinct advantages over the currently available $375+ million drug for wound debridement, presenting a unique opportunity for significant market growth.

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 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 EscharEx, 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 EscharEx 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 EscharEx; 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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[1] Primary research, Alira Health analysis (2025)