MediWound Announces Phase II Head-to-Head Study Evaluating EscharEx® vs. Collagenase in Patients with Venous Leg Ulcers

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Secured additional R&D collaborations with Solventum and Mölnlycke for optimal trial consistency and patient outcomes

Study to support EscharEx® BLA submission and strengthen commercialization strategy

YAVNE, Israel, Oct. 10, 2024 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair, today announced that it will be initiating a controlled, multicenter Phase II clinical study evaluating EscharEx® against collagenase ointment (marketed as SANTYL® in the U.S. and IRUXOL® in Europe) for the treatment of venous leg ulcers (VLUs). Scheduled to commence in 2025, this Phase II study will run concurrently with the Company's Phase III trial in VLU patients. The study is designed to support the Biologics License Application (BLA) for EscharEx and plays a key role in MediWound's commercialization strategy.

Ofer Gonen, CEO of MediWound, stated: "Building on the consistent positive results from three prior Phase II studies of EscharEx, we are eager to further validate our earlier findings from the head-to-head comparison vs. SANTYL, now on a larger, global scale. We are confident that EscharEx will demonstrate superior efficacy, addressing critical unmet needs in enzymatic debridement for patients with chronic wounds."

The randomized, prospective study will enroll 45 patients across multiple sites in the U.S. and Europe. VLU patients will be randomly assigned in a 1:1:1 ratio to receive either EscharEx, placebo, or collagenase. In the first two weeks, the EscharEx and placebo groups will receive up to 8 daily applications, while the collagenase group will follow the product's instructions for use (IFU). Each patient's participation will last up to 14 weeks. Key safety endpoints, including the incidence and severity of adverse events (AEs), and time to complete wound closure, will be assessed. Additionally, exploratory efficacy endpoints will evaluate the incidence and time to complete debridement, granulation tissue formation, and wound bed preparation.

To support this trial, MediWound has formed additional strategic R&D collaborations with Solventum and Mölnlycke Health Care. Solventum will supply the Coban™ 2 Two-Layer Compression System, while Mölnlycke will provide Mepilex®, Mepilex® Ag, Exufiber®, and Exufiber® Ag. These partnerships are designed to enhance consistency across study arms and ensure the use of best-in-class products, ultimately benefiting patient outcomes.

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. MediWound is set to initiate a Phase III study for Venous Leg Ulcers in the second half of 2024. Preparations for a Phase II/III study targeting Diabetic Foot Ulcers are underway.

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 rapid and effective biologics that enhance existing standards of care and improve patient experiences while reducing healthcare costs and unnecessary surgeries.

MediWound's first drug, NexoBrid ®, is FDA and EMA-approved as an orphan biologic for eschar removal in deep partial-thickness and/or full-thickness thermal burns, significantly reducing the need for surgical interventions. Building on its proprietary enzymatic platform, MediWound is advancing EscharEx®, a promising candidate currently in Phase III development for the debridement of chronic wounds. With distinct advantages over the current $360+ million market leader, EscharEx offers a unique opportunity for significant market expansion.

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, 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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