MediWound Announces Peer-Reviewed Publication of EscharEx® Mechanism of Action Study Assessing Its Effects on Biofilm and Microbial Loads

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Results show EscharEx to be safe and effective, and suggest it can go beyond traditional expectations for enzymatic debridement

YAVNE, Israel, Dec. 21, 2023 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair today announced the publication of a peer-reviewed paper, titled "*An Open-label, Proof of Concept Study, Assessing the Effects of Bromelain-Based Enzymatic Debridement on Biofilm and Microbial Loads in Patients with Venous Leg and Diabetic Foot Ulcers*" in the December 2023 issue of WOUNDS Journal.

The paper highlights results from a Phase II study, which explored the mechanism of action of EscharEx, a novel bromelain based enzymatic debridement agent, in 12 patients with either venous leg ulcers (VLUs) or diabetic foot ulcers (DFUs). Results show that EscharEx not only effectively debrides wounds, but also reduces biofilm and bacterial load in both VLUs and DFUs.

Key findings:

- 70% of the patients (7/10) that completed the study achieved complete debridement within a median time of 5.5 days. An average reduction of 35% in wound size was achieved by the end of the 2-week follow-up period.
- In all (100%) six patients positive for biofilm at baseline, EscharEx reduced the biofilm to a single individual or undetectable microorganisms, by the end of treatment based on tissue biopsies.
- Bacterial load was reduced by 64% following treatment with EscharEx based on a fluorescence imaging device.
- EscharEx was shown to be safe and well tolerated.

Dr. Rob Snyder, Chief Medical Officer of MediWound, emphasized the significance of these findings, stating, "Preparing a wound for closure in a timely fashion is critical to help reduce the burden associated with chronic wounds, including the potential downstream consequences of amputation and mortality. Together with the outcomes of our previous Phase II study results, this study furthers the understanding of the effects of EscharEx. It demonstrates its effectiveness not only in enzymatic debridement and promotion of granulation tissue, but potentially also in reducing biofilm and bacterial load. This dual mechanism of action may not only shift the disrupted healing process in chronic wounds towards a normal healing process, but may also prevent severe complications. We look forward to the initiation of the Phase III pivotal study in the second half of 2024 and, ultimately bringing this important non-surgical treatment to the millions of patients affected by chronic wounds."

About Biofilm

A biofilm is a complex and structured community of microorganisms (such as bacteria, fungi, and other microorganisms) that adhere to surfaces and are embedded in a self-produced extracellular matrix composed of proteins, polysaccharides, and DNA. These microorganisms are surrounded by a protective matrix, making them highly resistant to antibiotics, disinfectants, and the host immune response.

In the context of chronic wounds, biofilms play a significant role in hindering the healing process and contributing to persistent infections.

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 use in any patient setting, EscharEx is an easy-to-use concentrate of proteolytic enzymes enriched in bromelain for topical daily applications. In several 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 a few daily applications. EscharEx's mechanism of action is mediated by the proteolytic enzymes that cleave to, and remove the necrotic tissue preparing the wound bed for healing. The Phase III study, specifically on VLUs, will start in the second half of 2024.

About MediWound

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

MediWound's first drug, NexoBrid ®, is an FDA-approved orphan biologic for eschar removal in severe burns that can replace surgical interventions and minimize associated costs and complications. 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 debridement of chronic wounds with significant advantages over the $300 million monopoly legacy drug and an opportunity to expand the market. MediWound's pipeline also includes MW005, a topical therapeutic for the treatment of basal cell carcinoma that has demonstrated positive results in a recently completed Phase I/II study.

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, 2022, filed with the Securities and Exchange Commission ("SEC") on March 16, 2023 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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