# MediWound Announces Peer-Reviewed Paper Detailing EscharEx Phase 2 Randomized Control Trial Results Published in the Online Wound Repair and Regeneration Journal

July 9, 2021

*Study Findings Demonstrate Strong Results in Debriding Venous Leg Ulcers and Diabetic Foot Ulcers*

*Interim Assessment of Ongoing U.S. Phase II Adaptive Design Study in Venus Leg Ulcers Expected End of July 2021*

YAVNE, Israel, July 09, 2021 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation bio-therapeutic solutions for tissue repair and regeneration, today announced that a peer-reviewed publication, detailing the results of a phase 2 randomized control trial of its wound debriding product candidate EscharEx®, has been published in the *Wound Repair and Regeneration Journal*. An interim assessment of EscharEx's U.S. phase 2 adaptive design study for the treatment of venous leg ulcers (VLUs) is expected by end of July 2021.

The paper, entitled ***Bromelain-based enzymatic debridement of chronic wounds: Results of a multicenter randomized controlled trial***,[1] summarizes the results of a phase 2 assessor blinded study of EscharEx (first generation) for the debridement of chronic and hard-to-heal wounds. The study, conducted at 15 clinical sites in Israel and Europe, evaluated the safety and efficacy of EscharEx compared with a hydrogel vehicle in a variety of chronic and hard-to-heal wounds. Seventy-three patients suffering from lower extremity ulcers, such as diabetic foot ulcers (DFUs), venous legs ulcers (VLUs), and post-surgical or traumatic hard-to-heal wounds, were enrolled in this trial. Patients were randomized to topical treatment by either EscharEx or its gel vehicle for up to 10 daily 4-hour applications, and then continued follow-up for up to 6 months.

The EscharEx arm achieved a significantly higher incidence of complete debridement compared to the gel vehicle arm, thus meeting the primary endpoint of this study. The EscharEx and gel vehicle arms achieved similar reductions in wound area, non-viable tissue area, and wound healing scores during the debridement period. There were no significant differences between the arms in the incidence of complete wound closure and in the mean time to complete wound closure, and no significant safety issues were observed.

"We are very excited to have our phase 2 data published in this respected journal. The data clearly demonstrate that EscharEx debrides severe wounds rapidly and effectively with no deleterious effect on wound healing," said Sharon Malka, Chief Executive Officer of MediWound. "We believe EscharEx has the potential to improve on the current standard of care and have a meaningful impact on chronic wound management. We also look forward to the interim assessment of our U.S Phase 2 adaptive design study in venous leg ulcers as we continue to advance EscharEx's clinical development program."

**About EscharEx**

EscharEx, our bioactive therapy for debridement of chronic and other hard-to-heal wounds, is a product candidate in advanced stages of clinical development. EscharEx, a concentrate of proteolytic enzymes enriched in bromelain, is an easy-to-use product candidate, for topical daily applications, which designed for the outpatient setting.

In two phase 2 trials, EscharEx was well-tolerated and has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, with only few daily applications. The mechanism of action of EscharEx is mediated by the proteolytic enzymes that cleave and remove the necrotic tissue and prepare the wound bed for healing. EscharEx is an investigational product, currently under a U.S. phase 2 adaptive design study.

**About MediWound Ltd.**

MediWound is a biopharmaceutical company that develops, manufactures and commercializes novel, cost effective, bio-therapeutic solutions for tissue repair and regeneration. Our strategy leverages our enzymatic technology platform, focused on next-generation bioactive therapies for burn, wound care and tissue repair. NexoBrid®, our commercial orphan biological product for non-surgical eschar removal of deep, partial and full-thickness thermal burns, is a bromelain-based biological product containing a sterile mixture of proteolytic enzymes that selectively removes burn eschar within four hours without harming surrounding viable tissue. NexoBrid is currently marketed in the European Union and other international markets and is at registration-stage in the U.S. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx, our next-generation bioactive therapy for debridement of chronic and hard-to-heal wounds, is a product candidate in advanced stages of development. In two Phase 2 studies, EscharEx was well-tolerated and has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a few daily applications.

MW005, is a topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development.

Committed to innovation, we are dedicated to improving quality of care and patient lives. For more information, please visit www.mediwound.com.

***Cautionary Note Regarding Forward-Looking Statements***

*MediWound caution 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, objectives, expectations, and commercial potential of NexoBrid and EscharEx. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the timing and conduct of pre-clinical and clinical trials and product development activities; the timing or likelihood of regulatory approvals; the ability to successfully develop and commercialize NexoBrid, including its commercial growth potential and the market demand for the product; competitive developments; whether FDA will provide marketing approval for NexoBrid in the United States; the ability to successfully develop and commercialize EscharEx, the design of the Phase 2 study, the timing of the interim assessment, the impact of applicable laws and regulations; and the uncertainties associated with the scope, scale and duration of the impact of the COVID-19 pandemic. For example, we are unable to predict how the pandemic will affect the overall healthcare infrastructure, including the pace with which governmental agencies, such as the FDA, will review and approve regulatory submissions. Additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation efforts also may impact our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of NexoBrid 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, 2019, filed with the Securities and Exchange Commission ("SEC") on February 25, 2020, 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] *Bromelain-based enzymatic debridement of chronic wounds: Results of a multicentre randomized controlled trial - Shoham - - Wound Repair and Regeneration - Wiley Online Library*

Source: MediWound Ltd.