MediWound Completes Patient Enrollment for Interim Assessment of its U.S. EscharEx Phase 2 Adaptive Design Study

June 9, 2021

Interim Assessment Expected by end of July 2021 and Completion of Enrollment by Year-End 2021

YAVNE, Israel, June 09, 2021 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced that the enrollment target of patients for an interim assessment of its EscharEx® U.S. phase 2 adaptive design study for the treatment of venous leg ulcers (VLUs) has been achieved, and interim assessment is expected by the end of July 2021. The pre-defined interim assessment is for futility analysis and potential sample size adjustment. This study, which is targeted to enroll a total of 120 patients by year-end 2021, is designed to assess the safety and efficacy of EscharEx compared to gel vehicle (placebo control) and non-surgical standard-of-care (either enzymatic or autolytic debridement).

"We are very pleased to reach this important clinical milestone, and we look forward to the interim assessment next month," said Sharon Malka, Chief Executive Officer of MediWound. "With a clear unmet medical need for a non-surgical rapid and effective debridement agent in the outpatient setting, EscharEx has the potential to improve on the current standard of care and have a meaningful impact on chronic wound management. EscharEx represents a significant market opportunity for MediWound, with an addressable market of over a billion dollars annually."

As part of the Company's broader EscharEx development program, MediWound is also conducting a phase 2 open-label, single arm study assessing the pharmacological effects of EscharEx in up to 15 patients with both diabetic foot ulcers (DFUs) and VLUs. The objective of this study is to gain a better understanding of what is happening in the wound bed, both during and after debridement with EscharEx, and to assess its effect on biofilm burden, reduction in inflammation, and the initiation of wound healing. MediWound expects to generate data from this study in the second half of 2021.

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. On June 29, 2020, a biologics license application (BLA) was submitted to the U.S. FDA and was assigned a Prescription Drug User Fee Act (PDUFA) target date of June 29, 2021. 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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