MediWound Provides Progress Update on Its EscharEx Clinical Development Program

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Phase 2 Adaptive Design Study Sample Size Reduced to 120 Patients

Interim Assessment Expected in Mid-2021 and Completion of Enrollment by Year-End 2021

Protocol Submitted to FDA for Pharmacology Clinical Study with Data Expected in Second Half 2021

YAVNE, Israel, Jan. 11, 2021 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, today provided an update on its EscharEx® clinical development program.

Due to COVID-19 related enrollment delays and potentially future pandemic related implications on the conduct of its clinical studies, the company is accelerating its EscharEx phase 2 adaptive design study, for the treatment of venous leg ulcers (VLUs), by adjusting its enrollment target to 120 patients, down from the 174 originally planned. The sample size adjustment is supported by the assessment of the positive results generated in a recent in-vivo study, comparing EscharEx to a commercially enzymatic debriding agent, and the debridement efficacy results demonstrated in a previous phase 2 clinical study with first generation EscharEx. The company continues to actively recruit patients and reiterates its expectation for an interim assessment in mid-2021. As a result of the adjustment, study duration is expected to shorten and the company anticipates completing patient enrollment by year-end 2021.

MediWound recently submitted a protocol to the FDA for a pharmacology study and is preparing to initiate this study in the first half of 2021. The study is an open label, single arm study assessing the pharmacological effects of EscharEx in up to 15 patients with VLUs or diabetic foot ulcers (DFUs), including the effects on biofilm burden and wound inflammation, as well as the impact of EscharEx on wound healing progression. The company anticipates reporting data from this study in the second half of 2021.

"We are very pleased with the progress we have made in our EscharEx development program in 2020, despite the challenges posed by the COVID-19 pandemic," said Sharon Malka, Chief Executive Officer of MediWound. "Chronic wounds present a significant unmet medical need for many patients, and we believe that EscharEx can have a meaningful impact on chronic wound management, offering significant benefits for patients, healthcare professionals and payers. We welcome 2021 with great anticipation and look forward to the pharmacology study data as well as the interim assessment and completion of patient enrollment in our phase 2 adaptive design study."

About EscharEx
EscharEx is a topical biological drug candidate for the debridement of chronic and other hard-to-heal wounds. In two phase 2 trials, EscharEx has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a few daily applications. EscharEx active substance (API) is a concentrate of proteolytic enzymes enriched in bromelain. The mechanism of action of EscharEx is mediated by the proteolytic enzymes that cleaves and removes 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 fully integrated biopharmaceutical company focused on developing, manufacturing and commercializing novel therapeutics based on its patented proteolytic enzyme technology to address unmet needs in the fields of severe burns, chronic and other hard-to-heal wounds. MediWound's first innovative biopharmaceutical product, NexoBrid ®, non-surgically and rapidly removes burn eschar without harming viable tissue. The product has received marketing authorization from the European Medicines Agency as well as the Israeli, Argentinian, South Korean, Russian and Peruvian Ministries of Health for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns. On June 29, 2020, a biological 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. MediWound's second innovative product, EscharEx is a topical biological drug candidate for the debridement of chronic and other hard-to-heal wounds using the same proteolytic enzyme technology as NexoBrid. In two Phase 2 studies, EscharEx has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a few daily applications. 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 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 and the completion of enrollment, the time of commencing the pharmacological study and the results , 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 ability to recruit patients, the ability to conduct the studies in medical sites and 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 and EscharEx 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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