



Successful Completion of In-Vivo Head-to-Head Comparator Study of EscharEx versus a Commercial Enzymatic Debridement Agent

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Data to be Published in a Peer-Reviewed Journal in First Half 2021

YAVNE, Israel, Dec. 21, 2020 (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 announced the successful completion of a pre-clinical study designed to evaluate the debridement efficacy of EscharEx[®], a novel bromelain-based enzymatic debridement agent, in a porcine hard-to-heal wound model, and compare its efficacy with an FDA approved and commercially available collagenase enzymatic debridement agent. The study concluded that EscharEx treatment was more effective than the commercially available collagenase agent in removing eschars in this model. Results from the study will be published in a peer-reviewed journal in the first half of 2021.

"We are encouraged by the robust results of this in-vivo study comparing EscharEx to the commercially available enzymatic debriding agent," said Sharon Malka, Chief Executive Officer of MediWound. "Given the superior efficacy of EscharEx versus the comparator enzymatic debridement agent demonstrated in this study, as well as the positive safety and efficacy results generated in our previous phase 2 study, we believe EscharEx has the potential to become a game-changer in a sizeable market. EscharEx can have a meaningful impact on chronic wound management, offering significant benefits for patients, healthcare professionals and payers. We look forward to the publication of these study results in a peer-reviewed journal, and we continue to advance our U.S Phase 2 adaptive design study in venous leg ulcers."

The study, conducted in collaboration with a U.S. research center, was performed as part of MediWound's pharmacological evaluation of EscharEx's effect on chronic wounds, using a novel porcine eschar model designed to evaluate the efficacy of enzymatic debridement agents. The primary objective of the study was to compare the debridement efficacy of various concentrations of EscharEx, a novel bromelain-based enzymatic agent (second generation EscharEx formulation), with a commercially available collagenase debridement agent. Efficacy was evaluated based on the number of treatments of various concentrations of EscharEx and the collagenase agent needed to achieve complete eschar removal (greater than 95%), as assessed clinically.

With EscharEx treatment, complete eschar removal was achieved in all treated wounds, at all dose concentrations, within a maximum of ten 24-hour applications, and dose-dependency was observed in the time to complete debridement. After ten applications, the maximum number of applications needed to achieve complete eschar removal with EscharEx at its lower dose, none of the wounds treated with the collagenase enzymatic agent achieved complete eschar removal.

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 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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