



MediWound Announces Peer-Reviewed Publication of EscharEx In-Vivo Head-to-Head Comparator Study in the Journal of Wound Care

October 4, 2021

EscharEx Treatment Demonstrated Superior Efficacy in Debridement of Eschar

YAVNE, Israel, Oct. 04, 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 a peer-reviewed publication in the Journal of Wound Care of an in vivo head-to-head study comparing EscharEx® and a commercial enzymatic debridement agent in the removal of chronic wound eschar. The study concluded that EscharEx was more effective than the commercially available collagenase in removing the eschar in this wound model.

The paper, entitled *Development of a porcine chronic wound model: Evaluation of a bromelain-based enzymatic debriding agent*¹, describes the development of a novel porcine eschar model and compares the debridement efficacy of various concentrations of EscharEx, a novel bromelain-based enzymatic debridement agent, with commercially available collagenase-based debridement agent. Study results demonstrated that EscharEx treatment was more effective than the commercially available collagenase agent in debriding eschars in this novel porcine wound model.

"We are excited to have the study results published in this esteemed journal. The data clearly demonstrate EscharEx was superior to the commercially available enzymatic debriding agent in removing eschar," said Sharon Malka, Chief Executive Officer of MediWound. "The data generated to date, together with the successful interim assessment of our ongoing U.S. phase 2 study to treat patients with venous leg ulcers, give us confidence in our clinical development plan, and we look forward to report data from our phase 2 study in the first half of next year. EscharEx may offer significant benefits for patients and healthcare professionals in the care of chronic wounds, addressing a clear medical need for a rapid and effective non-surgical debridement agent, and we believe it has the potential to change the standard of care in this sizeable market."

Summary of study results

The study was conducted in collaboration with investigators from the Renaissance School of Medicine at Stony Brook University, Stony Brook, NY, using a novel porcine wound model designed to evaluate the efficacy of enzymatic debridement agents. The primary objective of the study was to assess the debridement efficacy of various concentrations of EscharEx, a novel bromelain-based enzymatic agent (second generation EscharEx formulation), and to compare it 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 necessary to achieve complete eschar removal (clinical assessment of at least 95% eschar removal from the center of the wound).

Key findings from the study included:

- In all wounds treated with EscharEx and at all concentrations, the wound eschar was completely removed within a maximum of ten 24-hour applications. A trend towards dose-dependency was observed in the time to complete debridement.
- None of the wounds treated with collagenase achieved >95% wound eschar removal after ten applications, the maximum number of applications needed to achieve complete debridement with EscharEx.
- Pairwise comparisons between wounds treated with collagenase and each of the concentrations of EscharEx demonstrated significantly fewer applications required to achieve complete eschar removal with EscharEx (adjusted $p < 0.05$).
- Analysis of variance comparing mean number of applications required to achieve complete eschar removal also showed significant differences in means in favor of EscharEx ($p < 0.001$).
- Pairwise comparisons between wounds treated with collagenase and each of the concentrations of EscharEx demonstrated significantly higher percentage of complete eschar removal with the EscharEx at all time points.

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 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.

EscharEx's 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 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 care, 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 is our next-generation bioactive topical therapeutic under development in the U.S. for debridement of chronic and hard to heal wounds. 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, our 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 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, objectives anticipated timelines, expectations and commercial potential of our products and product candidates. 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; our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets; timing or likelihood of approval by the U.S. Food & Drug Administration (FDA) of a Biologics License Application (BLA) for NexoBrid for treatment of severe burns in the United States following the receipt of a complete response for NexoBrid on June 28, 2021, 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; risks related to our contracts with BARDA, including availability of funding from BARDA; 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 COVID-19 pandemic on our business or the economy generally. For example, we are unable to predict how the COVID-19 pandemic will affect the overall healthcare infrastructure, including the ability to recruit patients, the ability to conduct the studies in medical sites and may impact the response times of governmental agencies, including the FDA, to future regulatory submissions and/or conduct necessary reviews or inspections of our manufacturing facilities, any or all of which may result in timelines being materially delayed, which could affect the development and ultimate commercialization of our products, including NexoBrid. Other disruptions or potential disruptions of the COVID-19 pandemic include restrictions on the ability of Company personnel to travel and access customers for training, promotion and case support, delays in product development efforts, and additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation efforts or initiatives that may impact our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of our products.

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, 2020, filed with the Securities and Exchange Commission ("SEC") on February 25, 2021, 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.

Contacts:	Jeremy Feffer
Boaz Gur-Lavie	Jeremy Feffer
Chief Financial Officer	Managing Director, LifeSci Advisors
MediWound Ltd.	212-915-2568
ir@mediwound.com	jeremy@lifesciadvisors.com

¹ <https://doi.org/10.12968/jowc.2021.30.Sup9a.VI>



Source: MediWound Ltd.