



MediWound's EscharEx Featured in Paper as a Potential Paradigm Shift Towards Non-Surgical Wound Bed Preparation in DFUs

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YAVNE, Israel, Nov. 09, 2022 (GLOBE NEWSWIRE) -- MediWound Ltd. (NASDAQ: MDWD), a fully integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced the publication of a paper, "Introducing Bromelain-Based Enzymatic Debridement" in the journal *Podiatry Management*. The paper reviewed past studies and summarized physicians' experiences in using EscharEx[®] for the debridement and wound bed preparation of Diabetic Foot Ulcers (DFUs).

EscharEx, MediWound's next generation topical debridement agent is a complex mixture of proteolytic enzymes enriched in bromelain developed for the treatment of chronic and other hard-to-heal wounds. Findings in the paper show EscharEx to be safe and effective, with over 50% of the patients achieving complete debridement within a week, and leaving the wounds with healthy granulation tissue. EscharEx was shown to be significantly more effective than the hydrogel control treatment. Similar results were found in the debridement of Venous Leg Ulcers (VLUs). This represents a potential paradigm shift from surgical debridement to a fast, effective, safe, practical and user-friendly treatment of chronic and hard to heal wounds.

"We were pleased to see that the physicians' experiences highlighted in this paper are similar to the results in our other EscharEx clinical trials," said Dr. Rob Snyder, Chief Medical Director of EscharEx. "We believe EscharEx, with its compelling efficacy and safety profile to date, has the potential to meaningfully impact the management and care of chronic wounds while offering significant benefits for patients and healthcare professionals. We look forward to its continued development."

DFUs are open sores or wounds that if not properly treated could become infected and require hospitalization. They are likely to affect and endanger up to 34% of diabetic patients at some stage in their lives. Early and effective debridement of the devitalized tissue is a cornerstone for wound healing and even patient survival. The current standard of care is based on two alternative debridement strategies: sharp (surgical) debridement or autolytic/enzymatic (non-surgical) debridement. Sharp debridement depends on trained medical professionals and adequate medical facilities; current enzymatic debridement depends on topical agents that require weeks of treatments, numerous dressing changes and are often ineffective.

About EscharEx

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

EscharEx was well-tolerated and demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds with only few daily applications in several Phase 2 trials. EscharEx's mechanism of action is mediated by the proteolytic enzymes that cleave and remove the necrotic tissue and prepare the wound bed for healing. A meeting with the FDA to discuss the Phase 3 pivotal study design is targeted for the fourth quarter of calendar year 2022.

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 is to leverage our enzymatic technology platform, focusing 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 the registration-stage with the United States Food and Drug Administration (FDA) with a PDUFA date set as of January 1, 2023. 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. EscharEx is 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 in several Phase 2 trials. A meeting with the FDA to discuss the Phase 3 pivotal study design is targeted for the fourth quarter of calendar year 2022.

MW005, our topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development. The initial data from a Phase I/II study showed MW005 to be safe and well-tolerated, with a majority of the patients who completed the study with MW005 achieving complete clinical and histological clearance of their target lesions. The Company anticipates announcing the final data in the fourth quarter of calendar year 2022.

Committed to innovation, we are dedicated to improving standard of care and enhancing 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, expected data timing, 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; the approval of regulatory submission by the European Medicines Agency, FDA or by any other regulatory authority, our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets. For example 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; 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. 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 our products and product candidates 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, 2021, filed with the Securities and Exchange Commission (“SEC”) on March 17, 2022, 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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