MediWound Announces Positive Initial Data from its U.S. Phase 2 Pharmacology Study of EscharEx Showing Effective and Rapid Debridement in Chronic and Hard to Heal Wounds

December 20, 2021

Data Demonstrate EscharEx Reduces Biofilm and Bacterial Burden
EscharEx is Shown to be Safe with No Observed Safety Issues

YAVNE, Israel, Dec. 20, 2021 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD) (the "Company"), a fully-integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced positive initial data from seven of the maximum fifteen patients in its ongoing open-label, phase 2 pharmacology study of EscharEx®, the company's next-generation enzymatic debridement agent under development for chronic and hard-to-heal wounds. The company expects to share the full data set from this study in the first half of 2022.

Based on the data generated to date, following treatment of seven patients with either diabetic foot ulcers (DFU's) or venous leg ulcers (VLU's), EscharEx demonstrated safe and effective debridement of lower leg ulcer within a few daily applications. In addition, evaluation of wounds' tissue samples (biopsies) and fluorescence images, indicated reduction of biofilm and bacterial load following the treatment with EscharEx.

"The data from this pharmacology study, which is in-line with the results of our previous phase 2 study in both VLU's and DFU's, clearly supports EscharEx as a potential triple threat in the treatment of chronic wounds with its effective wound debridement, disruption of biofilm, and reduction of bacterial load," said Sharon Malka, Chief Executive Officer of MediWound. "We believe that EscharEx, with its attractive product profile, can meaningfully improve wound care treatment over the current standard of care. Additionally, we look forward to sharing topline data from our ongoing EscharEx U.S. phase 2 adaptive design study in the first quarter of 2022."

Dr. Robert Snyder, Chief Medical Director of EscharEx program added "We are very pleased to see the initial data show that EscharEx could effectively debride wounds while disrupting biofilm and lowering bacterial bioburden. There is wide consensus among clinicians that infection and microbial biofilm impedes the healing process and prolongs wound healing. The pharmacology study provides us with a better understanding of what is happening in the wound bed, both during and after debridement with EscharEx."

The phase 2 pharmacology study, which remains ongoing, is a prospective, open label, single-arm study, being conducted at three U.S. clinical sites. The study is designed to evaluate the clinical performance, safety, and pharmacology effect of EscharEx in the debridement of lower leg ulcers (VLUs and DFUs) in up to fifteen patients. The study evaluates the safety and efficacy of debridement as measured by incidence of, and time to complete debridement. In addition, the study evaluates the pharmacological effects of EscharEx as measured by the changes from baseline to end of treatment period in (1) wound biofilm presence in wound biopsies, (2) bacterial burden measured by MolecuLight® fluorescence images, and (3) biomarkers of wound healing and inflammation in wound fluid.

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.

In two completed phase 2 trials, 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. 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. EscharEx is an investigational product and currently in a U.S. phase 2 adaptive design study.

About Biofilm[1]

Biofilm is created through the attachment of bacteria to elements in the extracellular polymeric substances (EPS). The EPS, which is 50% to 90% of the total biofilm organic matter, is comprised of dead host tissue, microorganisms' secretions, proteins, nucleic acids, lipids, and polysaccharides. Biofilms have been reported to interfere with normal wound healing, apparently by 'locking' the wound bed into a chronic inflammatory state that leads to elevated levels of tissue-degrading proteases and reactive oxygen species which damage cells and molecules needed for healing. A large percentage of bacteria in biofilm communities are metabolically dormant, and low metabolic rates make antibiotics ineffective. The EPS substances and their interactions are targets for therapeutic biofilm elimination.

Bacterial biofilms have been shown to prolong the inflammatory process, which is detrimental to wound healing because of the degradation of the growth factors required for cellular proliferation and migration necessary for wound healing.

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, 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, expected topline data timing, objectives anticipated timelines, expectations and commercial potential of our products and product candidates, including EscharEx. 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 EMA 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; 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, 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:
Boaz Gur-Lavie
Chief Financial Officer
MediWound Ltd.
ir@mediwound.com

Monique Kosse
Managing Director
LifeSci Advisors
212-915-3820
monique@lifesciadvisors.com

[1] Source: World Union of Wound Healing Societies (WUWHS), Florence Congress, Position Document. Management of Biofilm. Wounds International 2016

Source: MediWound Ltd.