MediWound Studying the Effect of EscharEx on Biofilm Burden

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Bromelain Degradation of Biofilms Could Provide Clinically Meaningful Benefits in Wound Healing

YAVNE, Israel, Oct. 14, 2020 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD) ("MediWound"), a fully-integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, today announced that it is exploring the pharmacological effect of EscharEx® on biofilm burden associated with chronic wounds based on the scientific evidence showing that enzymatic debridement might be an effective means to treat and reduce the biofilm burden.

The Unmet Medical Need[1]

Biofilms are aggregates of microorganisms encapsulated in a self-created matrix comprised of extracellular polymeric substances (EPS) wherein they are resistant to host defenses and antimicrobial agents. Biofilm has been reported to be present in 60%-100% of non-healing wounds and is associated with delayed wound healing, infection and other negative wound healing outcomes. The biofilm treatment market growth is primarily driven by the rising prevalence of chronic, surgical, and traumatic wounds as well by the increasing incidence of burn injuries. North America accounts for the largest share of this market.

Biofilm is recognized as a local component of the wound environment that requires removal to enable wound progression. Effective surgical debridement and reduction of the biofilm burden is now regarded as a first necessary step in the treatment of chronic wounds such as venous leg ulcers (VLU's), diabetic foot ulcers (DFU's) and pressure ulcers, prior to the application of advanced wound healing materials. While mechanical and surgical methods are commonly used due to their rapidness and specificity, these procedures can be associated with pain, collateral tissue damage, extended hospital stays, and high cost. Enzymatic debridement is an attractive alternative for certain patients because it is less painful, can be applied at the bedside, and has potential effectiveness against a broad range of bacterial wound pathogens.

As a result, the need for improved biofilm treatment strategies has renewed interest in developing enzymatic compounds for wound debridement and management with the added potential for disruption of EPS.

The Enzymatic Debridement Opportunity for Degradation of Biofilm

Multiple preclinical studies have reported that enzymes show promise as an effective treatment for reduction of the biofilm burden independent of its debridement capabilities. A paper published in the journal Infection and Drug Resistance entitled "*Enzymatic degradation of in vitro Staphylococcus aureus biofilms supplemented with human plasma*," (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4854256/) indicated that bromelain enzyme may be an effective mean of eradicating biofilm and a promising strategy to improve treatment of multidrug-resistant bacterial infections. In addition to removing necrotic tissue, enzymes may possess activity against proteins and bacterial or host DNA within the biofilm matrix.

EscharEx contains a mixture of proteolytic enzymes enriched in bromelain and has demonstrated in phase 2 clinical trials that it can effectively debride various chronic hard-to-heal wounds, within a few daily applications. Given its protease activity, MediWound believes it has the potential to reduce the biofilm burden by dispersing or inhibiting the formation of the EPS matrix. Therefore, MediWound has initiated plans to conduct pharmacological studies to assess the effect of EscharEx® on biofilm burden associated with chronic wounds.

"There is a wide consensus among clinicians that biofilm contributes to delays in wound healing. It has been shown that by targeting biofilm, wound healing could be improved," said Dr. Robert Snyder, Chief Medical Director of EscharEx program. "Elevating the standard of care utilizing innovative enzymatic debriding agents such as EscharEx, with the additional potential benefit of disrupting biofilm could provide an improved non-surgical treatment for this malady."

"The treatment of biofilm in chronic wounds is rapidly becoming a primary objective of wound care, with the presence of biofilm acknowledged as a leading cause of delayed wound healing," said Sharon Malka, Chief Executive Officer of MediWound. "We have reasons to believe that enzymes could become an important treatment in the eradication of biofilms, particularly in chronic wounds, and we believe that a potent, yet convenient, enzymatic debridement agent that can reduce the biofilm burden, could make a major impact on patients and on the worldwide healthcare burden that non-healing wounds cause. We look forward to exploring the effects of EscharEx on biofilm."

About Biofilm

Biofilm is created through the attachment of bacteria to elements in the 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 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 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. 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 EscharEx and its potential to reduce the biofilm burden by dispersing or inhibiting the formation of the EPS matrix. 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 and pharmacological trials and product development activities; the ability to successfully develop and commercialize EscharEx; 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.

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.

Certain data in this press release was obtained from various external sources, and neither MediWound nor its affiliates, advisers or representatives has verified such data with independent sources. Accordingly, neither MediWound nor any of its affiliates, advisers or representatives makes any representations as to the accuracy or completeness of that data or to update such data after the date of this press release. Such data involves risks and uncertainties and is subject to change based on various factors.

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[1] Source: World Union of Wound Healing Societies (WUWHS), Florence Congress, Position Document. Management of Biofilm. Wounds International 2016 (http://www.wuwhs2016.com/documents)

Source: MediWound Ltd.