



MediWound Announces Collaboration with Mölnlycke on EscharEx® Phase III Study

August 15, 2023

MediWound joins forces with one of the largest global chronic wound companies in pivotal study for patients with venous leg ulcers

YAVNE, Israel, Aug. 15, 2023 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully integrated biopharmaceutical company focused on next-generation enzymatic therapeutics for tissue repair, today announced a research collaboration agreement with Mölnlycke for its upcoming Phase III study of EscharEx® in venous leg ulcers (VLUs). Mölnlycke will provide Mepilex® Up, its most recent line extension to its global market leading brand, along with Exufiber® and Exufiber® Ag dressings to be used during the wound healing phase of the study.

"We've tailored our strategy for the upcoming Phase III VLU study in accordance with the U.S. Food and Drug Administration (FDA) recommendations to reduce variability. Restricting the number of wound dressing options is critical to successfully achieve the trial's endpoints. Mölnlycke's Mepilex dressings are the leading brand used worldwide in the largest category of wound dressings: foams," stated Dr. Robert Snyder, Chief Medical Officer, of MediWound. "Effective wound fluid management is crucial for the optimal healing of VLUs, which is why we are pleased to provide our study participants Mepilex Up, the most recent extension to the Mepilex line and specifically designed for this use."

EscharEx is being evaluated for efficacy and safety in the debridement of chronic wounds, with the first indication being VLUs. During the wound healing phase of the study, Mölnlycke's wound dressings will be used as standard of care in all study arms, until the wounds reach complete healing.

"Mepilex has been a market-leading brand for almost 20 years. With our recent launch of Mepilex® Up, we now can offer a unique dressing for use underneath compression systems. Given that MediWound's Phase III study is focusing on venous leg ulcers, this is the perfect setting in which to showcase this advanced dressing as the standard of care," stated Kacee Huguely, VP of US Wound Care Marketing of Mölnlycke. "We look forward to participating in this critical study and to supplying patients with our best-in-class dressings to help ensure optimal outcomes."

About EscharEx

EscharEx® (concentrate of proteolytic enzymes enriched in bromelain) is a topical biologic drug applied daily that enzymatically removes nonviable wound tissue, or eschar, in patients with chronic wounds without harming viable tissue. EscharEx has been the subject of 3 successful Phase 2 studies and is entering into a global Phase III study in early 2024. Co-primary endpoints in the study are incidence of complete debridement and time to complete wound closure. Secondary endpoints include time to complete debridement, incidence of complete granulation tissue, incidence of complete wound closure and wound area reduction.

About Mölnlycke

Mölnlycke is a world-leading medical products and solutions company that equips healthcare professionals to achieve the best patient, clinical and economic outcomes. We design and supply products and solutions for use in wound treatment, pressure injuries, infection prevention and surgery. Our products and solutions provide value and are supported by clinical and health economic evidence. For more information, please visit <https://www.molnlycke.us>.

About MediWound Ltd.

MediWound Ltd. (Nasdaq: MDWD) is the global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. Specializing in the development, production and commercialization of solutions that seek to replace existing standards of care, the Company is committed to providing rapid and effective biologics that improve patient experiences and outcomes, while reducing costs and unnecessary surgeries.

MediWound's first drug, NexoBrid®, is an FDA-approved orphan biologic for eschar removal in severe burns that can replace surgical interventions and minimize associated costs and complications. Utilizing the same core biotherapeutic enzymatic platform technology, MediWound has developed a strong R&D pipeline including the Company's lead drug under development, EscharEx®. EscharEx is a Phase III-ready biologic for debridement of chronic wounds with significant advantages over the \$300 million monopoly legacy drug and an opportunity to expand the market. MediWound's pipeline also includes MW005, a topical therapeutic for the treatment of basal cell carcinoma that has demonstrated positive results in a recently completed Phase I/II study.

For more information visit www.mediwound.com and follow the Company on [LinkedIn](#).

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, including EscharEx[®] and NexoBrid[®]. 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 FDA, the European Medicines Agency 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; market acceptance of our products and product candidates; our ability to maintain adequate protection of our intellectual property; competition risks; the impact of government laws and regulations and the impact of the current global macroeconomic climate on 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, 2022, filed with the Securities and Exchange Commission (“SEC”) on March 16, 2023 and 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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