MediWound Receives Positive Scientific Advice from European Medicine Agency (EMA) on EscharEx Phase III Study Design

July 3, 2023

Affirms the clear path forward for the Company's global Phase III study of EscharEx in venous leg ulcers

YAVNE, Israel, July 03, 2023 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation enzymatic therapeutics for tissue repair, today announced it has received positive scientific advice from the Committee for Medicinal Products for Human Use (CHMP) within the European Medicines Agency (EMA) related to the development plan for the company's Phase III study of EscharEx in the treatment of Venous Leg Ulcers (VLUs) and to the overall data required for subsequent potential marketing authorization submission and commercialization.

The CHMP notified the company that it concurs with the overall design of the proposed study, including its objectives, choice of study arms, patient population, inclusion/exclusion criteria, standardization of treatment, proposed primary, secondary, and safety endpoints and study duration. Additionally, the CHMP indicated that it can accept one confirmatory study in VLU patients as the basis for approval, assuming the data are robust and similar to the company's previous studies.

"We are very pleased to receive positive Scientific Advice from EMA supporting our Phase III development plan for EscharEx. The constructive feedback we have garnered from both the U.S. Food and Drug Administration (FDA) and the EMA provides consensus, empowering us to conduct this pivotal Phase III study on a global scale," said Ofer Gonen, Chief Executive Officer of MediWound. "EscharEx addresses an important medical need for patients suffering from chronic wounds, and we look forward to bringing this next-generation therapy to market."

In this initial indication for EscharEx, VLUs affect approximately 560,000 patients annually with an estimated $1 Billion market in the U.S. alone. The Phase III study will be a global, multi-center, prospective, randomized, placebo-controlled trial in approximately 244 patients, who will be randomized to either EscharEx or gel vehicle (placebo control) in a 1:1 ratio. The treatment protocol will include a daily visit period of up to 14 days, during which EscharEx or gel vehicle will be applied once a day for a maximum of 8 applications lasting 24 hours each. Patients will then be followed weekly for up to 10 weeks, during which time they will be treated with standard of care (SOC). Patients who achieve wound closure confirmation will continue for an additional 10-week follow-up. The co-primary endpoints are the incidence of complete debridement at the end of the daily visit period, and time to achieve wound closure. EscharEx uses the same active pharmaceutical ingredient (API) as the NexoBrid®, which has been approved for debridement of thermal burns in the U.S. and Europe.

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 biologic for debridement of chronic wounds with significant advantages over the $300 million monopoly legacy drug and an opportunity to expand the market. Additionally, MediWound has a Phase I/II biologic for basal cell carcinoma, MW005, with results expected in Q3 2023.

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; 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 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.

Investor Contacts:

Hani Luxenburg
Chief Financial Officer
MediWound, Ltd.
ir@mediwound.com

Monique Kosse
Managing Director, LifeSci Advisors
+1-212-915-3820
monique@lifesciadvisors.com