MediWound Announces Collaboration with MIMEDX on EscharEx® Phase III Study

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MediWound to join forces with leading chronic wound allograft company 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 it has entered into a research collaboration agreement with MIMEDX Group, Inc (Nasdaq: MDXG). MIMEDX will provide its market leading placental tissue allograft EPIFIX® to be used during the wound healing phase of the EscharEx® Phase III study in venous leg ulcers (VLUs).

"For our Phase III study, the U.S. Food and Drug Administration (FDA) emphasized the importance of minimizing product variation in the wound healing process. Existing data clearly demonstrates notable differences in outcomes depending on the allograft used," explained Ofer Gonen, Chief Executive Officer of MediWound. "We are thrilled to offer patients in our study a market-leading and extensively studied allograft, EPIFIX. By incorporating EPIFIX into the trial, we aim to maintain consistency among study subjects and optimize the potential for complete healing throughout the study duration."

EscharEx is being evaluated in a Phase III study for efficacy and safety in the debridement of chronic wounds in VLUs, the first indication being studied. In the trial, once a subject's wound is completely debrided and the wound bed is covered with 100% granulation tissue, the patient will have either an autograft (a minor surgical procedure using the patient's own tissue as the graft) or allograft (some form of donated tissue) applied to the wound to facilitate complete closure.

Joseph H. Capper, Chief Executive Officer of MIMEDX stated, "We are excited to collaborate with MediWound on this important study. Their expertise and success in developing and bringing debridement biologics to market, coupled with the strong body of evidence we have generated for EPIFIX over the years, positions this Phase III study in VLUs as a significant milestone in the wound care field. Notably, there have been no new FDA-approved drugs in this category since 1997. Being the largest and most comprehensive VLU study in the past decade, we anticipate this well-structured trial will provide invaluable evidence-based insights to the advanced wound care industry," added Capper.

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 MIMEDX

MIMEDX (Nasdaq: MDXG) is a pioneer and leader focused on helping humans heal. With more than a decade of helping clinicians manage chronic and other hard-to-heal wounds, MIMEDX is dedicated to providing a leading portfolio of products for applications in the wound care, burn, and surgical sectors of healthcare. The Company's vision is to be the leading global provider of healing solutions through relentless innovation to restore quality of life. For additional information, please visit www.mimedx.com.

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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