MediWound Announces Positive Results in Head-to-Head Comparison of EscharEx® vs. SANTYL® within the ChronEx Phase II Randomized Controlled Study

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Results demonstrate superiority of EscharEx®, a bromelain-based gel vs. SANTYL®, a collagenase ointment, in wound debridement, promotion of granulation tissue, and time to wound closure in patients with chronic venous leg ulcers (VLU)

YAVNE, Israel, Feb. 12, 2024 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair today announced the results of head-to-head comparison analyses of EscharEx, the Company's lead asset in development for chronic wounds, to collagenase SANTYL ointment, approved by the FDA for debriding chronic dermal ulcers. SANTYL is currently the market-leading enzymatic debridement product, with more than $360 million in estimated annual sales in the United States.

Results from the previously disclosed Phase II study (ChronEx) which evaluated the safety and efficacy of EscharEx, demonstrated the superiority of EscahrEx vs. a gel vehicle (placebo) and non-surgical standard of care (NSSOC), in achieving complete debridement of non-viable tissue and promotion of granulation tissue (healthy, highly vascularized tissue). The secondary analyses announced today assessed the incidence and time to complete debridement, complete granulation, and wound closure in patients treated with EscharEx (n=46) compared to a sub-group of patients who were treated with SANTYL (n=8).

Ofer Gonen, CEO of MediWound said, "These head-to-head results position EscharEx to become the market leader in enzymatic agents for the treatment of chronic wounds. Data from clinical studies show that EscharEx provides a multimodal mechanism of action for debridement and promotion of granulation tissue, as well as reduction of biofilm and bioburden. All are achieved within a short time frame to facilitate early wound closure, a major benefit for patients suffering from chronic non-healing wounds. With such promising Phase II data, we look forward to the upcoming Phase III trial, set to begin in the second half of 2024, as planned."

Results highlights (EscharEx vs SANTYL)

- Baseline characteristics (age, gender, wound age, wound size) were comparable in both groups.
- The incidence of complete debridement during the *daily treatment period* (the first two weeks of the study) was 63.0% (95% CI=47.5-76.8) for EscharEx vs. 0% for SANTYL; p=0.001.
- The estimated median time to achieve complete debridement during the study was 9 days (95% CI=5-15 days) for EscharEx vs. not achieved for SANTYL (95% CI=22-Not Applicable); p=0.023.
- The incidence of achieving complete debridement and complete cover of the wound bed with granulation tissue (i.e., wound bed preparation, WBP) during the daily treatment period was 50.0% (95% CI = 34.9%-65.1%) for EscharEx vs. 0% for SANTYL; p=0.015.
- The incidence of achieving WBP throughout the study was 78.3% (95% CI = 63.6-89.1) for EscharEx vs. 37.5% for SANTYL (95% CI=8.5-75.5); p=0.03.
- The estimated median time to achieve WBP was 11 days (95% CI =7-50 days) for EscharEx vs. not achieved for SANTYL (95% CI=22-Not Applicable); p=0.014.
- 15 of the 46 patients (32.6%) treated with EscharEx completely closed their wounds during the study, compared to 2 out of 8 patients (25%) treated with SANTYL (NSS). In those patients who achieved complete wound closure, the average time to wound closure was 48.4 days (SD=23.5) for EscharEx vs. 76.0 days (SD=2.8) for SANTYL; p=0.05.
- Patient reported applicational pain was comparable in both groups.
- The safety profile and overall incidence of adverse wound reactions were comparable between arms.

Dr. Robert J. Snyder, Chief Medical Officer of MediWound added, "Complete debridement and complete granulation are key components of wound bed preparation, a critical step in the transition of a chronic wound from an abnormal, disrupted healing process to a normal healing process. These results further support the potential superiority of EscharEx compared with SANTYL in both the percentage of wounds achieving these critical steps, as well as the timeframe in which they are achieved. These significant differences could have a profound impact on wound healing, prevention of complications, and reduction in disease burden."

The data is scheduled for presentation in May 2024 at three leading annual congresses dedicated to advanced wound care: The Wound Healing Society (WHS), the Symposium on Advanced Wound Care (SAWC), and the European Wound Management Association (EWMA).

About the ChronEx study

The ChronEx study was a Phase II multicenter, prospective, randomized, placebo controlled, adaptive design study that evaluated the safety and efficacy of a bromelain-based enzymatic debridement agent in debridement of Venous Leg Ulcers (VLUs).

In the ChronEx study, patients with chronic VLU were randomized (3:3:2 ratio) to daily treatment with EscharEx, placebo, or non-surgical standard of care (SOC), respectively, for up to 2 weeks or until reaching complete debridement and then treated with non-surgical SOC for 12 weeks. The non-surgical SOC arm included SANTYL®, hydrogels, medical grade honey, and non-active dressings.

About EscharEx

EscharEx is a bioactive, multimodal debridement therapy for the treatment of chronic and other hard-to-heal wounds, currently in the advanced stages of clinical development. It is a concentrate of proteolytic enzymes enriched in bromelain for topical, easy to use daily applications. In several Phase II trials, EscharEx was shown to be safe, well-tolerated, and demonstrated its efficacy in debridement and promotion of granulation tissue in various hard-to-heal wounds, with only a few daily applications. EscharEx's mechanism of action is mediated by proteolytic enzymes that cleave to and remove the necrotic tissue preparing the wound bed for healing. Phase III study in patients with VLU, is planned to start in the second half of 2024.

About MediWound

MediWound Ltd. (Nasdaq: MDWD) is the global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. MediWound specializes in the development, production and commercialization of solutions that seek to improve 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 potential advantages over the $360 million dominant product 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 and X.

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®. 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 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.

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