MediWound Completes Enrollment of its EscharEx U.S. Phase 2 Adaptive Design Study

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Topline Data Expected in the First Quarter of 2022

YAVNE, Israel, Dec. 06, 2021 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD) (the "Company"), a fully-integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced it has completed patient enrollment in its U.S. Phase 2 adaptive design clinical study evaluating the safety and efficacy of EscharEx® in debridement of venous leg ulcers (VLUs) compared to gel vehicle (placebo control) and non-surgical standard-of-care (either enzymatic or autolytic debridement).

In July 2021, the Company reported a positive outcome from its planned interim assessment on sample-size re-estimation for this study, conducted after 80 patients were treated, with no changes to the original study sample size of 120 patients and no safety concerns identified. Topline data from clinical study is now anticipated in the first quarter of 2022.

"Completing enrollment in our U.S. phase 2 trial is an important step in advancing EscharEx as a non-surgical rapid and effective debridement agent with the potential to improve on the current standard of care for chronic wound management," said Sharon Malka, Chief Executive Officer of MediWound. "Chronic wound care is a significant market opportunity for us with an addressable market of over one billion dollars annually, and we believe EscharEx could be a meaningful part of that market. We look forward to sharing topline data from this study in the first quarter of 2022."

Dr. Robert Snyder, Chief Medical Director of EscharEx program added, "We are pleased to see EscharEx move forward in its development as a potential therapy for people suffering from chronic wounds. We thank our partners, the investigative staff, and especially the patients and families for their commitment and perseverance in completing enrollment in the face of all the challenges posed by the pandemic."

The study is a multicenter, prospective, randomized, placebo-controlled, adaptive design study, evaluating the safety and efficacy of EscharEx in debridement of VLUs. The study enrolled 120 patients at approximately 20 clinical sites, primarily in the U.S. Study participants were randomized to either EscharEx, placebo control or non-surgical standard-of-care of either enzymatic or autolytic debridement, at a ratio of 3:3:2, with a three-month follow-up. The primary endpoint is incidence of complete debridement compared to gel vehicle placebo control. Secondary endpoints include time to achieve complete debridement, reduction of pain, reduction of wound area, granulation tissue and quality of life. Incidence and time to achieve wound closure will be assessed as safety measurements.

The study included a pre-defined interim assessment for futility and potential sample size adjustment. The Independent Data Monitoring Committee's (IDMC) conducted the pre-specified interim conditional power assessment, after 80 patients out of the originally targeted of 120 patients completed the debridement treatment and recommended that no changes to the original enrollment target of 120 patients was required to maintain the pre-specified statistical power of 80 percent or greater on the study's primary endpoint of incidence of complete debridement compared with gel vehicle. In addition, the IDMC reviewed the data of all subjects treated and no safety concerns were identified in the study population.

As part of the Company's broader EscharEx development program, MediWound is also conducting a phase 2 open-label, single arm study assessing the pharmacological effects of EscharEx in up to 15 patients with both diabetic foot ulcers (DFUs) and VLUs. The objective of this study is to gain a better understanding of what is happening in the wound bed, both during and after debridement with EscharEx, and to assess its effect on biofilm burden, reduction in inflammation, and the initiation of wound healing. MediWound expects to generate data from this study in the second half of 2021.

About EscharEx

EscharEx is a bioactive therapy for debridement of chronic and other hard-to-heal wounds in advanced stages of clinical development. Designed for the outpatient setting, EscharEx is an easy-to-use concentrate of proteolytic enzymes enriched in bromelain for topical daily applications.

In two already completed phase 2 trials, EscharEx was well-tolerated and has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds with only few daily applications. EscharEx's mechanism of action is mediated by the proteolytic enzymes that cleave and remove the necrotic tissue and prepare the wound bed for healing. EscharEx is an investigational product and currently in a U.S. phase 2 adaptive design study.

About MediWound Ltd.

MediWound is a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, bio-therapeutic solutions for tissue repair and regeneration. Our strategy leverages our enzymatic technology platform, focused on next-generation bioactive therapies for burn care, wound care and tissue repair.

NexoBrid, our commercial orphan biological product for non-surgical eschar removal of deep-partial and full-thickness thermal burns, is a bromelain-based biological product containing a sterile mixture of proteolytic enzymes that selectively removes burn eschar within four hours without harming surrounding viable tissue. NexoBrid is currently marketed in the European Union and other international markets and is at registration-stage in the U.S. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx, our next-generation bioactive topical therapeutic under development in the U.S. for debridement of chronic and hard to heal wounds. In two Phase 2 studies, EscharEx was well-tolerated and has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a few daily applications.

MW005, our topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development.

Committed to innovation, we are dedicated to improving quality of care and patient lives. For more information, please visit www.mediwound.com.

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 topline 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 EMA 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 COVID-19 pandemic. For example, we are unable to predict how the pandemic will affect the overall healthcare infrastructure, including the ability to recruit patients, the ability to conduct the studies in medical sites and the pace with which governmental agencies, such as the FDA, will review and approve regulatory submissions. Additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation efforts also may impact 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, 2020, filed with the Securities and Exchange Commission ("SEC") on February 25, 2021, 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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