MediWound Enrolls First Patient in Phase 2 Pharmacology Study of EscharEx

April 22, 2021

Data Expected Second-Half 2021

YAVNE, Israel, April 22, 2021 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation bio-therapeutics solutions for tissue repair and regeneration, today announced it has enrolled the first patient in its phase 2 pharmacology study of EscharEx®, its next-generation enzymatic debridement agent under development for chronic wounds, with data expected in the second half of 2021.

The pharmacology study, to be conducted in 2-3 U.S. clinical sites, is a phase 2 prospective, open label, single arm study. The objective of the study is to evaluate the clinical performance, safety, and pharmacology effect of EscharEx in debridement of lower leg ulcers (venous leg ulcers and diabetic foot ulcers) in up to 15 patients. Data collection includes the effects on biofilm burden and wound inflammation, as well as the impact of EscharEx on wound healing progression.

“Chronic wounds represent a significant unmet medical need for many patients, and EscharEx, with its positive safety and efficacy results generated in our previous phase 2 studies, can have a meaningful impact on chronic wound management, offering significant benefits for patients, healthcare professionals and payers,” said Sharon Malka, Chief Executive Officer of MediWound. “We anticipate data from the pharmacology study in the second half of this year, in addition to the interim assessment in our EscharEx phase 2 adaptive design study.”

“There is wide consensus among clinicians that infection and microbial biofilm impedes the healing process and prolongs wound healing. The treatment of biofilm in chronic wounds is rapidly becoming a primary objective of wound care,” said Dr. Robert Snyder, Chief Medical Director of EscharEx program. “EscharEx may convert a chronic wound into one that is acute while also disrupting biofilm and planktonic bacteria, which could delay wound healing.”

About EscharEx

EscharEx is a topical biological drug candidate for the debridement of chronic and other hard-to-heal wounds. In two phase 2 trials, EscharEx has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a few daily applications. EscharEx active substance (API) is a concentrate of proteolytic enzymes enriched in bromelain. The mechanism of action of EscharEx is mediated by the proteolytic enzymes that cleaves and removes the necrotic tissue and prepare the wound bed for healing. EscharEx is an investigational product, currently under a U.S. phase 2 adaptive design study.

About Biofilm[1]

Biofilm is created through the attachment of bacteria to elements in the extracellular polymeric substances (EPS). The EPS, which is 50% to 90% of the total biofilm organic matter, is comprised of dead host tissue, microorganisms’ secretions, proteins, nucleic acids, lipids, and polysaccharides. Biofilms have been reported to interfere with normal wound healing, apparently by ‘locking’ the wound bed into a chronic inflammatory state that leads to elevated levels of tissue-degrading proteases and reactive oxygen species which damage cells and molecules needed for healing. A large percentage of bacteria in biofilm communities are metabolically dormant, and low metabolic rates make antibiotics ineffective. The EPS substances and their interactions are targets for therapeutic biofilm elimination.

Bacterial biofilms have been shown to prolong the inflammatory process, which is detrimental to wound healing because of the degradation of the growth factors required for cellular proliferation and migration necessary for wound healing.

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 is centered around our validated enzymatic platform technology, focused on next-generation bio-active therapies for burn and wound care and biological medicinal products for tissue repair.

NexoBrid, our first commercialized product for non-surgical and rapid eschar removal of deep, partial and full-thickness thermal burns without harming viable tissue, is currently marketed in the European Union and other International markets. On June 29, 2020, a BLA was submitted to the FDA and was assigned a PDUFA target date of June 29, 2021. NexoBrid is supported by 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.

MediWound's third innovative product candidate, MWPC005, is a topical drug candidate under development for the treatment of non-melanoma skin cancer.

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 caution 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, 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; 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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[1] Source: World Union of Wound Healing Societies (WUWHS), Florence Congress, Position Document. Management of Biofilm. Wounds International 2016

Source: MediWound Ltd.