MediWound Announces Initiation of U.S. Phase I/II Study of MW005 for the Treatment of Basal Cell Carcinoma

July 26, 2021

Data Expected End of 2021

Phase II Investigator-Initiated Trial in Non-Melanoma Skin Cancers Running in Parallel

YAVNE, Israel, July 26, 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 initiation of its phase I/II study of MW005 for the treatment of low-risk Basal Cell Carcinoma (BCC). In parallel, an investigator-initiated phase II trial of MW005 in non-melanoma skin cancers is being conducted at the Soroka Medical Center in Israel. MediWound expects that data from both studies will be available by the end of 2021.

The phase I/II open-label, randomized clinical study is designed to evaluate the safety and tolerability of MW005 in BCC using different schedules of administration, as well as to provide a preliminary evaluation of its efficacy, as measured by the percentage of target lesions with complete histological clearance. The study will enroll up to 32 patients with histologically confirmed superficial or nodular BCC and will be conducted at three leading clinical centers in the United States.

The phase II investigator-initiated trial is an open-label study, designed to evaluate the safety and efficacy of MW005 in removing non-melanoma skin cancers and pre-cancerous lesions (e.g., actinic keratosis, BCC, and squamous cell carcinoma) in up to 50 patients.

“Most low-risk BCCs are treated surgically. There is a clear unmet need for an effective, non-surgical, topically-applied, short duration treatment for low-risk BCC, with less severe local skin reactions associated with current topical therapies,” said Dr. Brian Berman, past president of American Dermatological Association, Professor Emeritus, University of Miami, and a lead principal investigator of the phase I/II study. “We are pleased to lead the clinical evaluation of MW005 as a potentially impactful topical therapy for low-risk BCC, given its pro-apoptotic mechanism of action and preliminary proof-of-concept efficacy.”

“We are excited to initiate this U.S. phase I/II study of MW005, which is the first step in this important clinical development program. MW005 represents a meaningful progress in our strategy to leverage our innovative enzymatic technology platform to pioneer solutions for unmet medical needs,” said Sharon Malka, Chief Executive Officer of MediWound. "We are encouraged by the interest expressed by the clinical community to participate in this study, and we look forward to working closely with practitioners and patients as we advance this program to potentially treat the most common form of human cancer.”

BCC is a non-melanoma skin cancer that arises from the basal layer of epidermis and its appendages. According to the American Cancer Society, BCC is the most diagnosed skin cancer in the United States with approximately 4.3 million cases diagnosed every year. The increasing number of diagnosed BCC is a result of better skin cancer detection, increased sun exposure, and greater life expectancy.

About MW005

MW005, a topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development. MW005 is based on a proprietary formulation, designed to ease self-administration by the patients, and is based on the same active substance as in NexoBrid® and EscharEx®, a concentrate of proteolytic enzymes enriched in bromelain.

The clinical development program of MW005 is supported by results from several toxicological and other preclinical studies, as well as the vast clinical experience with NexoBrid and EscharEx. In addition, a recently-published case series, wherein MW005 (a concentrate of proteolytic enzymes enriched in bromelain) was used for destruction of basal cell carcinoma, provides a preliminary clinical proof-of-concept that MW005 may be a safe and effective treatment in this indication.

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 burns, 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 therapy for debridement of chronic and hard-to-heal wounds, is a product candidate in advanced stages of development. 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, with only 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 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 MW005. 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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