MediWound Announces Positive Initial Data from its U.S. Phase I/II Study of MW005 for the Treatment of Basal Cell Carcinoma

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MW005 Shown to Be Safe and Well-Tolerated
Target Lesions Clearance Data Provides Clinical Efficacy Proof-of-Concept

YAVNE, Israel, July 11, 2022 (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 positive initial data from eleven patients in its ongoing open-label Phase I/II study of MW005 for the treatment of low-risk Basal Cell Carcinoma (BCC). The initial data shows MW005 to be safe and well-tolerated, with a majority of the patients who completed the study achieving complete histological clearance of their target lesions following treatment with MW005. The Company anticipates announcing the final data in the second half of 2022.

In the first cohort, eleven patients with either superficial or nodular BCC were treated. Patients enrolled into the study received seven topical applications of MW005, once every other day. At the end of eight weeks post treatment period, all patients undergo complete excision, and the specimen is subject to an independent histological clearance examination. Based on the data generated to date, MW005 is safe, well-tolerated and an effective treatment for BCC with a majority of patients who completed the study demonstrating a complete histological clearance of target lesions.

"Non-melanoma skin cancers are the most common of all types of cancer and represent a significant potential market opportunity for MediWound," said Ofer Gonen, Chief Executive Officer of MediWound. "We recognize that there is a high unmet need for a non-surgical treatment that achieves high rates of clinical and histological clearance with a safe profile. The data continues to validate our technology, providing us with multiple strategic alternatives to advance the development of this asset."

Prof. Lior Rosenberg, Chief Medical Technology Officer at MediWound said, "These encouraging results from the Phase I/II clinical trial of MW005 suggest that we are on a path to potentially offer a topical treatment for patients with BCC that would be an alternative to surgical excision of these lesions. The data is in line with the previously published clinical experience we had and provides further clinical proof-of-concept."

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 U.S. Phase I/II Study

The Phase I/II open-label single-arm clinical study is designed to evaluate the safety and efficacy of MW005 in BCC using different schedules of administration. The study is comprised of two cohorts of up to 16 adult patients each, with histologically confirmed superficial or nodular BCC. Patients enrolled into the study received seven topical applications of MW005, once every other day. Following the completion of the treatment course, patients are followed-up for eight weeks in which healing status of the wound and adverse events are assessed by the PI. At the end of eight weeks post treatment, all patients undergo complete excision, and the specimen is subject to an independent histological clearance examination. The study's endpoints include safety and tolerability measurements, as well as efficacy, as measured by the proportion of patients who reach a clinically assessed complete clearance and with complete histological clearance confirmation. The study is being conducted at three leading clinical centers in the United States.

About MW005

MW005 is a topical biological drug under development for the treatment of non-melanoma skin cancers. Its proprietary formulation is designed to ease self-administration and is based on the same active pharmaceutical ingredient 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 clinical case series published in a peer review paper, 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 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 with the Food and Drug Administration (FDA). 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. 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 in several Phase 2 trials. An end-of-phase 2 meeting with the FDA is targeted for the second half of 2022.

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 data timing, 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; the approval of regulatory submission by 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; 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, 2021, filed with the Securities and Exchange Commission ("SEC") on March 17, 2022, 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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