



MediWound Announces Positive Results in 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

Data provide clinical efficacy proof-of-concept based on clearance of target lesions

YAVNE, Israel, July 10, 2023 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation enzymatic therapeutics for tissue repair, today announced positive data from its Phase I/II study to evaluate the safety and efficacy of MW005 in the treatment of low-risk Basal Cell Carcinoma (BCC). The data show MW005 to be safe and well-tolerated, with patients achieving complete clinical and histological clearance of their target lesions.

The Phase I/II study is an open-label, multi-centered, randomized clinical trial designed to evaluate the safety and efficacy of MW005 in patients with BCC. All of the patients enrolled in the study had histologically confirmed superficial or nodular BCC. Enrolled patients received seven topical applications of MW005 once every other day for fourteen days. Eight weeks following the last treatment, all patients underwent a complete excisional biopsy. The excised specimen was subjected to an independent histological clearance examination. The study's endpoints include safety and tolerability measurements, as well as efficacy assessments, as measured by the proportion of patients who reach clinically and histologically confirmed complete clearance.

Fifteen patients were treated with MW005 and completed the study. Results showed MW005 to be safe and well-tolerated, with a high level of patient compliance. While the primary focus of the trial was on safety and tolerability, it is worth noting that based on clinical assessments, eleven out of fifteen patients achieved complete clearance of their BCCs; the majority of these patients also had histologically confirmed complete clearance. Data comprising clinical and histological outcomes, supported by extensive patient follow-up, will be featured at an upcoming scientific conference in 2023.

These results corroborate the previous proof-of-concept study published by Prof. Rosenberg et al (*Basal Cell Carcinoma Destruction by a Concentrate of Proteolytic Enzymes Enriched in Bromelain: A Preliminary Report*; [TODJ-15-39](#), 2021), where seven BCC tumors treated with MW005 were completely removed based on clinical assessment, and none reoccurred over the subsequent 24 months.

"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 a superior tolerability profile, 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. "These encouraging results from the clinical study of MW005 suggest that we are headed in the right direction and on track for a possible solution."

Ofer Gonen, CEO of MediWound, said, "These data further validate the potential of MW005 as a significant advancement in cancer treatment. BCC affects two to three million individuals in the U.S. each year, and we believe MW005 may reduce the reliance on expensive and potentially disfiguring surgical procedures in certain cases, thereby improving patient experiences and outcomes."

About MediWound Ltd.

MediWound Ltd. (Nasdaq: MDWD) is the global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. Specializing in the development, production and commercialization of solutions that seek to replace 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 advantages over the \$300 million monopoly legacy drug 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](#).

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 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 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.

Contacts:

Hani Luxenburg
Chief Financial Officer
MediWound Ltd.
ir@mediwound.com

Monique Kosse
Managing Director, LifeSci Advisors
212-915-3820
monique@lifesciadvisors.com