



## MediWound Announces Positive Results in U.S. Phase I/II Study of MW005 for the Treatment of Basal Cell Carcinoma

December 19, 2022

*MW005 shown to be safe and well-tolerated*

*Data provides clinical efficacy proof-of-concept based on complete clearance of target lesions*

YAVNE, Israel, Dec. 19, 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 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 shows MW005 to be safe and well-tolerated, with patients achieving complete clinical and histological clearance of their target lesions. MW005 contains the same active pharmaceutical ingredient as in NexoBrid® and EscharEx®. The results of this study represent further demonstration of the efficacy of MediWound's core enzymatic platform technology across various indications. Based on these positive results, MediWound plans to continue enrolling patients in its Phase I/II study, optimizing its dosing regimen and application technique. The results are expected in 2023.

The Phase I/II study is an open-label, multicenter, randomized clinical trial designed to evaluate the safety and efficacy of MW005 in patients with BCC, using different regimens. All patients enrolled in the study must have histologically confirmed superficial or nodular BCC. Enrolled patients receive seven topical applications of MW005 once every other day for 14 days. Eight weeks after the last treatment, all patients undergo a complete excisional biopsy, and the specimen is subject to an independent histological clearance examination. The study's endpoints include safety and tolerability measurements, as well as efficacy assessment, as measured by the proportion of patients who reach clinically and histologically confirmed complete clearance.

Eleven patients with either superficial or nodular histologically diagnosed BCC lesions were treated and completed the study. Based on the data generated, MW005 was shown to be safe, well-tolerated, and an effective treatment for BCC with patients demonstrating complete clinical and histological clearance of target lesions. These results corroborate with previous POC IIT 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 18 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 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 solution."

Ofer Gonen, Chief Executive Officer of MediWound, said: "These results once again demonstrate the potential of our innovative enzymatic platform technology to pioneer solutions for unmet medical needs. While MediWound remains focused on the continued growth of NexoBrid and the advancement of our EscharEx program, we are excited about the potential of MW005 to become an effective treatment for BCC, and other indications with similar etiologies. We look forward to advancing the development of this novel topical treatment, most likely with strategic partners."

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 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 to leverage our enzymatic technology platform, focusing 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 the registration-stage with the United States Food and Drug Administration (FDA) with a target PDUFA date set for January 1, 2023. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx, based on the same active pharmaceutical ingredient as NexoBrid, is our next-generation bioactive topical therapeutic under development for the debridement of chronic and hard-to-heal wounds. Results from Phase 2 studies show that EscharEx is significantly more effective and faster than SOC or placebo control in debridement of VLU and DFUs, with a good safety and tolerability profile. MediWound has initiated discussions with the FDA regarding the EscharEx pivotal Phase 3 study design.

MW005 is our topical biological drug under development for the treatment of low-risk Basal Cell Carcinoma (BCC). Its proprietary formulation is designed for safe and easy self-administration. It contains the same active pharmaceutical ingredient as NexoBrid and EscharEx. In a Phase I/II open-label, multicenter, randomized clinical trial conducted in the U.S., MW005 was shown to be safe, well-tolerated, and an effective treatment for BCC with patients demonstrating complete clinical and histological clearance of target lesions.

Committed to innovation, we are dedicated to improving standard of care and enhancing patient lives. For more information, please visit [www.mediwound.com](http://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 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 market potential, 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 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, 2021, filed with the Securities and Exchange Commission (“SEC”) on March 17, 2022, quarterly Reports of Foreign Private Issuer 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:**

Boaz Gur-Lavie  
Chief Financial Officer  
MediWound Ltd.  
[ir@mediwound.com](mailto:ir@mediwound.com)

Monique Kosse  
Managing Director  
LifeSci Advisors  
212-915-3820  
[monique@lifesciadvisors.com](mailto:monique@lifesciadvisors.com)

