



## MediWound Launches Clinical Development Program for Treatment of Non-Melanoma Skin Cancer

February 22, 2021

*Phase I/II Clinical Study in Basal Cell Carcinoma Scheduled to Begin Second Quarter 2021, with Data Expected by the End of 2021*

*An Investigator-Initiated Trial Will Run in Parallel*

**YAVNE, Israel, Feb. 22, 2021 (GLOBE NEWSWIRE)** -- MediWound Ltd. (Nasdaq: MDWD), a fully integrated biopharmaceutical company focused on next-generation bio-therapeutic solutions for tissue repair and regeneration, today announced the initiation of a new clinical development program to evaluate its drug product candidate MWPC005 in patients with non-melanoma skin cancer. MediWound recently submitted a protocol to the FDA for a phase I/II clinical study of MWPC005 for the treatment of basal cell carcinoma (BCC) and is preparing to initiate this study in the United States in the second quarter of 2021. A phase II investigator-initiated trial of MWPC005 in non-melanoma skin cancer will be conducted in parallel at the Soroka Medical Center in Israel. MediWound expects that data from both studies will be generated by the end of 2021.

MWPC005 is a topically applied biological drug candidate based on the same active ingredient as in the Company's NexoBrid<sup>®</sup> and EscharEx<sup>®</sup> products, a concentrate of proteolytic enzymes enriched in bromelain. MediWound's preclinical in-vitro research, combined with existing scientific evidence in a skin cancer model, demonstrated bromelain's anti-cancer activity, and together with clinical case studies suggest that MWPC005 might have a role in treating low-risk non-melanoma skin malignancies.

"I am pleased to launch our new clinical development program for the treatment of non-melanoma skin cancers. MWPC005 represents an important step in our strategic evolution to leverage our innovative enzymatic platform technology to pioneer solutions for unmet medical needs," said Sharon Malka, Chief Executive Officer of MediWound. "Non-melanoma skin cancers, including BCC, are by far the most common of all types of cancer and represent a significant potential market opportunity. We believe that MWPC005 has the potential to be an effective non-invasive treatment for BCC without the side effects associated with current topical therapies and their longer treatment duration. While MediWound remains focused on its continued growth and advancement of our NexoBrid and EscharEx programs, we are excited to add a synergistic drug product candidate to our pipeline portfolio."

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 diagnosed cases every year. The increasing number of diagnosed BCC is a result of better skin cancer detection, increased sun exposure, and greater life expectancy.

The phase I/II open-label, randomized clinical study of MWPC005 in BCC is designed to evaluate safety and tolerability using different schedules of administration, as well as provide a preliminary evaluation of efficacy as measured by the percentage of target lesion 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 U.S.

The phase II investigator-initiated trial is an open-label study, designed to evaluate the safety and efficacy of MWPC005 in removing non-melanoma skin cancer and pre-cancerous lesions (e.g. actinic keratosis, BCC and squamous cell carcinoma) in up to 50 patients.

### About MWPC005

MWPC005, is a topically applied biological product candidate based on the same active substance as in NexoBrid<sup>®</sup> and EscharEx<sup>®</sup> products, a concentrate of proteolytic enzymes enriched in Bromelain. MWPC005 is based on a proprietary formulation, designed to ease self-administration by the patients. The clinical development plan of MWPC005 is supported by the results from several toxicological and other preclinical studies, as well as the vast clinical experience from NexoBrid and EscharEx, which share the same active substance.

### 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 biological 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 biologics license application (BLA) was submitted to the U.S. FDA and was assigned a Prescription Drug User Fee Act (PDUFA) target date of June 29, 2021. NexoBrid is supported by 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. 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 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](http://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, objectives, expectations, and commercial potential of our products and product candidates. 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 preclinical studies and 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; 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, 2019, filed with the Securities and Exchange Commission ("SEC") on February 25, 2020, 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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