



MediWound Announces Peer-Reviewed Paper of a Case Series Report of Basal Cell Carcinoma Published in the Open Dermatology Journal

June 7, 2021

Findings Provide Preliminary Proof-of-Concept

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

YAVNE, Israel, June 07, 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 that a peer-reviewed publication of a case series report of basal cell carcinoma (BCC) destruction by a concentrate of proteolytic enzymes enriched in bromelain has been published in the Open Dermatology Journal. MediWound anticipates initiating a phase I/II clinical study of MW005 for the treatment of BCC this month, with data expected by the end of 2021.

The paper, entitled [Basal Cell Carcinoma Destruction by a Concentrate of Proteolytic Enzymes Enriched in Bromelain: A Preliminary Report \(opendermatologyjournal.com\)](https://opendermatologyjournal.com), details case series experience using a concentrate of proteolytic enzymes enriched in bromelain for the destruction of six BCC tumors. Six BCCs located on the face, neck, and extremities were self-treated by three patients with 2-6 applications. All of the BCCs were completely removed and two of the lesion's sites were surgically excised after 6 months with no tumor cells noted on histopathology. None of the BCCs recurred over the subsequent year. The findings provide a preliminary proof-of-concept that a concentrate of proteolytic enzymes enriched in bromelain may be a safe and effective destructive treatment for basal cell carcinomas.

"We are very excited to have our case series data published in a peer reviewed paper," said Prof. Lior Rosenberg, Chief Medical Technology Officer of MediWound. "The data provide a preliminary evaluation of MW005 efficacy as a destructive treatment for BCC, which we plan to further evaluate in our planned clinical studies. These clinical experiences, combined with our pre-clinical in-vitro research and existing scientific evidence, suggest that MW005 might have a role in treating low-risk non-melanoma skin malignancies."

"Non-melanoma skin cancers are by far the most common of all types of cancer and represent a significant potential market opportunity," said Sharon Malka, Chief Executive Officer of MediWound. "We are pleased with the positive data, which establish the foundation for our non-melanoma skin cancer clinical development plan. We believe that MW005 has a reasonable path to market with a clear unmet medical need, and the clinical plan we have laid out carries relatively low development costs given its active substance which has wealth of pre-clinical and clinical data and the intended indication."

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.

About MW005

MW005, is a topically applied biological product candidate based on the same active substance as in NexoBrid® and EscharEx® products, a concentrate of proteolytic enzymes enriched in bromelain. MW005 is based on a proprietary formulation, designed to ease self-administration by the patients. The clinical development plan of MW005 is supported by 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, MW005, 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.

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; 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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