



EMA Provides Regulatory Path for Pediatric Label Extension for NexoBrid

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Anticipate Submission for Label Extension in First Half 2022

YAVNE, Israel, Nov. 18, 2021 (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 that the Company has received positive scientific advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) related to the pediatric label extension for NexoBrid. Based on the feedback, the Company anticipates submitting a pediatric label extension request in the first half of 2022.

EMA's CHMP agreed to assess a potential pediatric label extension on NexoBrid for the treatment of thermal burns, based on the available safety and efficacy results of the pivotal phase 3 pediatric clinical study (CIDS – Children Innovation Debridement Study) with its 12-month follow-up, and that the long-term follow up data are likely to be supportive data.

"We are very pleased to have received support and positive guidance from the CHMP on the regulatory pathway towards a pediatric label extension for NexoBrid," said Sharon Malka, Chief Executive Officer of MediWound. "Having a non-surgical option for these severely burned young patients will be a significant step forward over the current surgical standard of care, which involves painful surgery with long recovery times. NexoBrid growth in Europe has been strong, and with the potential pediatric label extension, our commercial team and distribution partners are looking forward to expanding the market and continuing to improve on the standard of care."

Summary of Phase 3 CIDS study

The study met its three primary endpoints with a high degree of statistical significance. NexoBrid demonstrated a significant reduction in time to achieve complete eschar removal and significant reduction in wound area requiring surgical excision (surgical need) while demonstrating non-inferiority to SOC in quality of scars. The study also met certain secondary endpoints showing statistically significant reduction in the incidence of surgical excision and reduction in need for autograft in deep partial burns, as well as a favorable trend in reduction of blood loss during the eschar removal process. In addition, the study showed that NexoBrid was safe and well-tolerated.

Funding and support for this pivotal pediatric Phase 3 clinical study (CIDS) with NexoBrid is provided by the Biomedical Advanced Research and Development Authority (BARDA), under the office of the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing contract number HHSO100201500035C.

About NexoBrid

NexoBrid (concentrate of proteolytic enzymes enriched in Bromelain) is a topically administered biological product that enzymatically removes nonviable burn tissue, or eschar, in patients with deep partial and full-thickness thermal burns within four hours of application without harming viable tissue. NexoBrid is approved in the European Union and other international markets and has been designated as an orphan biologic drug in the United States, European Union, and other international markets. Vericel holds an exclusive license for North American commercial rights to NexoBrid. In January 2019, MediWound announced positive top-line results from the acute phase of the pivotal Phase 3 U.S. clinical study (DETECT) of NexoBrid in adult patients with deep partial-and full-thickness thermal burns up to 30 percent of total body surface area. The study met its primary endpoint of complete eschar removal compared to gel vehicle as well as all secondary endpoints compared to standard of care (SOC), including shorter time to eschar removal, a lower incidence of surgical eschar removal and lower blood loss during eschar removal. Safety endpoints, including the key safety endpoint of non-inferiority in time to complete wound closure compared with patients treated with SOC, were also achieved. In addition, the twelve-month and twenty- four-month follow-up safety data of cosmesis and function were found to be comparable between the treatment and SOC arms, and no new safety signals were observed. NexoBrid is currently an investigational product in the United States.

About MediWound Ltd.

MediWound is a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, biotherapeutic 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 in the U.S. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx is 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.

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, regulatory submissions, objectives, anticipated timelines, expectations and commercial potential of our products and product candidates, including NexoBrid. 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 EMA 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, 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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