EMA Accepts MediWound's Application for Extended Indication for NexoBrid to Treat Pediatric Patients with Severe Thermal Burns

September 20, 2022

Upon approval, NexoBrid will serve as a safe and effective non-surgical treatment option in the EU for children with severe burns

YAVNE, Israel, Sept. 20, 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 that the European Medicines Agency (EMA) has validated for review the Type II Variation submitted by MediWound in order to expand the current approved indication for NexoBrid (removal of eschar in adults with deep partial-and full-thickness thermal burn wounds) into the pediatric population. MediWound expects a decision from the European Commission in the first quarter of 2023.

EMA has initiated evaluation of the application to extend the use of NexoBrid to children aged newborn through eighteen. The submission is supported by the interim results of a global, Phase 3 trial (CIDS - Children Innovative Debridement Study), evaluating the safety and efficacy of NexoBrid in hospitalized pediatric patients, and by additional data available from children who participated in the EU phase 3 study (MW2004-11-02) and phase 2 studies conducted during the clinical development of NexoBrid.

"Today's announcement reflects our long-term commitment to elevating burn care to a higher dimension. Adding pediatric burn victims is significant as they comprise more than 30% of the total burn population. The current standard of care is extremely traumatic to patients, as well as their families. NexoBrid enables clinicians to provide a safe, fast, and highly effective debridement option, independent of surgery, that addresses an unmet need in burn care, especially in the pediatric population," said Ofer Gonen, Chief Executive Officer of MediWound.

In July 2021, MediWound announced the results from the CIDS trial, a Phase 3, multinational, randomized, multicenter, open label, controlled, 2 arm study performed in children with deep partial thickness and full thickness thermal burns of 1% to 30% of total body surface area (TBSA).

Top line Results demonstrated that the CIDS study successfully met its primary endpoint and secondary endpoints with a comparable safety profile to the standard of care. NexoBrid safety profile in children is consistent with the safety profile in adults. Patients' follow-up is on-going.

NexoBrid development has been supported with federal funding from U.S. Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing contract numbers HHSO100201500035C and HHSO100201800023C. Contract number HHSO100201500035C provides funding and technical support for the pivotal U.S. Phase 3 clinical study (DETECT) and the marketing approval registration process for NexoBrid as well as its procurement and availability under the expanded access treatment protocol (NEXT) in the U.S. Additional projects for evaluation of NexoBrid funded under the BARDA contract include the randomized, controlled pivotal clinical trial for use in the pediatric population (CIDS), establishment of a pre-emergency use data package and development of the health economic model to evaluate the cost savings impact to enable market adoption in the United States.

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 41 countries in the European Union and other international markets and is at registration-stage with the Food and Drug Administration (FDA). NexoBrid 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. 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% of total body surface area 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. In addition, MediWound announced Positive Topline Results from Phase 3 Pediatric Study (CIDS) of NexoBrid for Eschar Removal of Severe Thermal Burns with NexoBrid® to treat children with severe thermal burns, evaluating the efficacy and safety compared with standard-of-care (SOC). 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 with No deleterious effect on wound healing was observed. Patients' follow-up is on-going.

About MediWound

MediWound is a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, bio-therapeutic 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 with the Food and Drug Administration (FDA). 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. EscharEx is 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 in several Phase 2 trials. A meeting with the FDA to discuss the pivotal study design is targeted for the second half of 2022.

MW005, our topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development. The initial data from a Phase I/II study showed MW005 to be safe and well-tolerated, with a majority of the patients who completed the study with MW005 achieving complete histological clearance of their target lesions. The Company anticipates announcing the final data in the second half of 2022.

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, expected data timing, 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 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; 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, 202 1, filed with the Securities and Exchange Commission ("SEC") on March 17, 2022, 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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