MediWound Receives Complete Response Letter from U.S. FDA for NexoBrid Biologics License Application

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Company Remains Committed to Working with FDA Toward a Potential Approval for this Important Therapy

YAVNE, Israel, June 29, 2021 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation bio-therapeutics solutions for tissue repair and regeneration, today announced it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the Biologics License Application (BLA) seeking approval of NexoBrid® for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns.

The FDA communicated that it had completed its review of the BLA, as amended, and has determined that the application cannot be approved in its present form. The FDA identified issues related to the Chemistry, Manufacturing and Controls ("CMC") section of the BLA and requested additional CMC information. The FDA acknowledged receipt of several CMC amendments, submitted in response the CMC information requests, which were not reviewed for this action.
The FDA also stated that an inspection of NexoBrid's manufacturing facilities in Israel and Taiwan, are required before the FDA can approve the BLA, but it was unable to conduct the required inspections during the current review cycle due to COVID-related travel restrictions. The FDA stated that it will continue to monitor the public health situation as well as travel restrictions and is actively working to define an approach for scheduling outstanding inspections. In addition, the CRL cited certain observations identified during good clinical practice (GCP) inspections related to the U.S. Phase 3 study (DETECT), and requested the company to provide its perspective on the potential impact, if any, of these observations on the efficacy findings in the study. The FDA also requested to provide a safety update as part of its BLA resubmission, although there were no safety issues raised in the CRL.

"While we are disappointed that the FDA has issued a CRL for NexoBrid, we remain confident in the strength of our clinical data and in the depth of our development program," said Sharon Malka, Chief Executive Officer of MediWound. "We remain committed to working collaboratively with the Agency, as well as BARDA, to identify the most expeditious pathway toward a potential approval for this important therapy. We believe that, upon approval, NexoBrid will benefit severe burn victims in routine care and serve as a critical medical countermeasure in case of a U.S. mass casualty incident."

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 Corporation (NASDAQ: VCEL) holds an exclusive license for North American commercial rights to NexoBrid. Funding and technical support for the development of NexoBrid is being provided by the U.S. Biomedical Advanced Research and Development Authority (BARDA), including the ongoing expanded access protocol (NEXT) in the U.S., which allows for the continued clinical use of NexoBrid during FDA's review of the NexoBrid BLA. In addition, BARDA procured NexoBrid for the U.S. emergency stockpile as part of its mission to build national preparedness for public health emergencies.

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, bio-therapeutic solutions for tissue repair and regeneration. Our strategy leverages our enzymatic technology platform, focused on next-generation bioactive therapies for burn, 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, our next-generation bioactive therapy for debridement of chronic and hard-to-heal wounds, is a product candidate in advanced stages of development. 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, with only 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.

About BARDA

The Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies. For more information, refer to www.phe.gov/about/BARDA. Funding and technical support for development of NexoBrid to obtain marketing approval in the U.S. including the expanded access treatment protocol (NEXT), the pivotal U.S. Phase 3 clinical study (DETECT) and the marketing approval registration process for NexoBrid in the U.S. is provided by BARDA, under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. HHSO100201500035C. Additional projects for evaluation of NexoBrid funded under the BARDA contract include randomized, controlled pivotal clinical trial for use in pediatric population, 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.

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," "futu re," "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 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; 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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