



MediWound Announces U.S. FDA Acceptance of Biologics License Application for NexoBrid for the Treatment of Severe Thermal Burns

August 3, 2022

Prescription Drug User Fee Act (PDUFA) target date of January 1, 2023

YAVNE, Israel, Aug. 03, 2022 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD) ("MediWound"), a fully-integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review its recently re-submitted Biologics License Application (BLA) for NexoBrid® for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns. The FDA assigned a Prescription Drug User Fee Act (PDUFA) target date of January 1, 2023.

"We are thrilled to have our application accepted and to be one step closer to commercializing NexoBrid in the U.S. We have seen NexoBrid help burn patients worldwide and knowing that it may be soon available in the United States is very gratifying," said Ofer Gonen, CEO of MediWound. "We thank both Vericel and BARDA for their leadership and commitment to this important program."

The BLA re-submission adds to the set of manufacturing data, preclinical and clinical studies previously submitted. These include extensive scrutiny of the pivotal U.S. Phase 3 (DETECT) study of NexoBrid in adult patients with deep partial and/or full-thickness thermal burns up to 30% of total body surface area. The DETECT study successfully met its primary endpoint and all secondary endpoints with a comparable safety profile to the standard of care. NexoBrid is approved in the European Union and other international markets. It has been designated as an orphan biologic drug in the United States, European Union, and other international markets. NexoBrid is currently an investigational product in the United States. Vericel Corporation (NASDAQ: VCEL) holds an exclusive license for North American commercial rights to NexoBrid.

NexoBrid development has been supported in part with federal funding from U.S. Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG 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 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.

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. 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.

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 product candidates; 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, 2021, 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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Source: MediWound Ltd.