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

September 16, 2020

YAVNE, Israel, Sept. 16, 2020 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD) (the "MediWound"), a fully-integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review its recently 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 June 29, 2021. In addition, the FDA communicated that it is not currently planning to hold an advisory committee meeting to discuss the application.

"The FDA's acceptance of the NexoBrid BLA submission for review is a major milestone for MediWound, and it is gratifying to know NexoBrid is one step closer to being available to help burn victims in the United States," said Sharon Malka, CEO of MediWound. "We thank all our partners for their commitment to this important program, and we look forward, together with BARDA and Vericel, to working with the FDA during the regulatory review process as we seek marketing approval for NexoBrid in the United States."

Nick Colangelo, President and CEO of Vericel, added, "The FDA's acceptance of the NexoBrid BLA for review represents another important milestone toward our goal of providing a new standard of care for eschar removal in patients with severe burns and brings us one step closer to providing NexoBrid as a treatment option for the thousands of patients each year who suffer deep-partial and full-thickness burns that require debridement."

The BLA submission includes a comprehensive set of manufacturing data, multiple preclinical and clinical studies including 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. 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. 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. Funding and technical support for the development of NexoBrid is being provided by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

Vericel, our U.S. commercial partner, will host a virtual Analyst and Investor Day on Friday, October 16, 2020, from 9:00 a.m. - 11:00 a.m. EST which will focus on NexoBrid, which will include discussions with burn surgeon thought leaders on current burn debridement practices and how NexoBrid, upon approval, could change the current treatment paradigm for debridement of severe thermal burns.

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 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. On June 29, 2020, a BLA was submitted to the U.S. FDA seeking the approval for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns. Additional twenty-four-month long term safety follow up data will be submitted as a safety labeling update as part of a post-approval commitment.

About MediWound
MediWound is a fully-integrated biopharmaceutical company focused on developing, manufacturing and commercializing novel therapeutics based on its patented proteolytic enzyme technology to address unmet needs in the fields of severe burns, chronic and other hard-to-heal wounds. MediWound's first innovative biopharmaceutical product, NexoBrid ®, non-surgically and rapidly removes burn eschar without harming viable tissue. The product has received marketing authorization from the European Medicines Agency as well as the Israeli, Argentinian, South Korean, Russian and Peruvian Ministries of Health. MediWound's second innovative product, EscharEx ® is a topical biological drug candidate for the debridement of chronic and other hard-to-heal wounds using the same proteolytic enzyme technology as NexoBrid. In two Phase 2 studies, EscharEx has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a few daily applications. 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 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 the Biomedical Advanced Research

and Development Authority (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 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, objectives, expectations, and commercial potential of NexoBrid and EscharEx. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the timing and conduct of clinical trial and product development activities; the timing or likelihood of regulatory approvals; the ability to successfully develop and commercialize NexoBrid, including its commercial growth potential and the market demand for the product; the availability of funding from BARDA under its agreement with MediWound for use in connection with NexoBrid development activities; the timing of the NexoBrid delivery to BARDA, expected payments under the license agreement with Vericel; competitive developments; whether FDA will accept all or part of the BLA and provide marketing approval for NexoBrid in the United States; the risks related to the timing and conduct of NEXT Study; the ability to successfully develop and commercialize EscharEx, the design of the Phase 2 study, the timing of the interim assessment, the impact of applicable laws and regulations; and the uncertainties associated with the scope, scale and duration of 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 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 NexoBrid 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, 2019, filed with the Securities and Exchange Commission ("SEC") on February 25, 2020, 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.