MediWound and Vericel Announce Acceptance of the First Delivery of NexoBrid to BARDA for Emergency Response Preparedness

August 25, 2020

YAVNE, Israel and CAMBRIDGE, Mass., Aug. 25, 2020 (GLOBE NEWSWIRE) -- MediWound Ltd. (NASDAQ: MDWD) and its U.S. commercial partner Vericel Corporation (NASDAQ: VCEL) today announced that the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services, has accepted the first shipment of NexoBrid® (concentrate of proteolytic enzymes enriched in Bromelain) as part of its mission to build national preparedness for public health emergencies. The initial BARDA procurement of NexoBrid is valued at $16.5 million, which includes additional quarterly deliveries planned through the end of 2021. In addition, BARDA holds an option to procure additional quantities of NexoBrid through funding of up to $50 million.

“This first shipment of NexoBrid is another major milestone in our longstanding partnership with BARDA, and we look forward to delivering the full procurement by the end of 2021,” said MediWound Chief Executive Officer Sharon Malka. “The acceptance of the first delivery by BARDA during the ongoing COVID-19 pandemic underscores the importance of NexoBrid to U.S. national preparedness for the potential emergency treatment of large numbers of patients with severe thermal burns injuries.”

“The procurement of NexoBrid for our nation’s response preparedness is one of many key NexoBrid activities occurring in 2020,” said Nick Colangelo, President and Chief Executive Officer of Vericel. “This shipment, combined with the recent BLA submission and growing number of burn centers enrolled in the NexoBrid expanded access treatment protocol, bring us a step closer to ensuring that healthcare providers have both the supply and training needed to enzymatically debride burn patients, whether the need is due to individual accidents or a burn mass casualty event.”

On June 30, 2020, a Biologics License Application (BLA) was submitted to the U.S. Food and Drug Administration (FDA) seeking the approval of NexoBrid for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns. While the BLA is being reviewed by the FDA, burn centers across the U.S. are treating burn patients under the NexoBrid expanded access (NEXT) protocol.

The procurement is a key milestone of the Project BioShield (PBS) contract between MediWound and BARDA which was signed in September 2015 with procurement initiated in January 2020. Under the PBS contract, BARDA provides funds and support for the advancement of the development and manufacturing of NexoBrid, as well as the procurement of NexoBrid as a medical countermeasure for mass casualty emergencies involving thermal burns. In May 2019, Vericel entered into exclusive license and supply agreements with MediWound to commercialize NexoBrid in North America. As part of the license agreement, Vericel and MediWound will equally split gross profits generated by BARDA’s initial $16.5 million procurement.

In October 2019, MediWound initiated the NEXT protocol, which is supported and funded by BARDA and enables the continued clinical use of NexoBrid for U.S. patients during the preparation and review of the NexoBrid BLA. NEXT is an open-label, single-arm treatment protocol which allows for the treatment of up to 150 burn patients with deep partial- and full-thickness thermal burns up to 30 percent of total body surface area. NEXT has been designed to be consistent with current real-life burn treatment practices in the U.S. and up to 30 U.S. burn centers are anticipated to participate. MediWound received FDA concurrence that patients can be treated under the NEXT protocol in a burn mass casualty incident that is not a declared national emergency. Therefore, this provides a mechanism for U.S. burn centers to treat patients and gain valuable experience using Nexobrid prior to FDA approval as well as making the product readily available for response to mass burn emergencies.

BARDA submitted a Pre-Emergency Use Authorization (PEUA) to FDA for the intended use of NexoBrid under an Emergency Use Authorization (EUA) during a declared emergency involving burn injuries. The availability of medical countermeasures (MCMs), such as Nexobrid, which mitigate preparedness gaps (like debridement and excision steps of burn care) will add to the United States Government’s armamentarium for treatment of mass burn casualties. The EUA is a mechanism by which the FDA can allow an unapproved medical product that qualifies as a mass casualty medical countermeasure to be used in a public health emergency.

About NexoBrid
NexoBrid 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. NexoBrid is currently an investigational product in the United States.

About Vericel Corporation
Vericel is a leader in advanced therapies for the sports medicine and severe burn care markets. The company markets two cell therapy products in the United States. MACI® (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. Epicel® (cultured epidermal autografts) is a permanent skin replacement for the treatment of patients with deep dermal or full-thickness burns greater than or equal to 30% of total body surface area. The company also holds an exclusive license for North American commercial rights to NexoBrid, a registration-stage biological orphan product for debridement of severe thermal burns. For more information, please visit the company’s website at www.vcel.com.

About MediWound Ltd.
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
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
This document contains forward-looking statements, including statements concerning the anticipated progress, development, objectives, expectations and commercial potential of NexoBrid. This release also includes forward-looking statements concerning the objectives and expectations regarding MediWound Ltd. and Vericel Corporation described herein, all of which involve certain risks and uncertainty. 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. Actual results may differ significantly from the expectations contained in the forward-looking statements.

Among the factors that may result in differences 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; the availability of funding from BARDA under its agreement with MediWound for use in connection with NexoBrid development activities; 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 our NEXT; 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. 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, Quarterly Reports on Form 6-K and other filings with the Securities and Exchange Commission ("SEC"), as well as information contained in Vericel's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on February 25, 2020, Quarterly Reports on Form 10-Q and other documents filed by the Company with the SEC from time-to-time.

These forward-looking statements reflect Vericel's and MediWound's current views and neither Vericel nor MediWound undertakes any obligation to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.

Vericel Contacts:
Lee Stern
Solebury Trout
lstern@troutgroup.com
+1 (646) 378-2922

MediWound Contacts:
Boaz Gur-Lavie
Chief Financial Officer
MediWound Ltd.
ir@mediwound.com

Jeremy Feffer
Managing Director, LifeSci Advisors
212-915-2568
jeremy@lifesciadvisors.com

Source: MediWound Ltd.