BARDA Initiates the Procurement of NexoBrid for Emergency Response

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YAVNE, Israel and CAMBRIDGE, Mass., Jan. 06, 2020 (GLOBE NEWSWIRE) -- MediWound Ltd. (NASDAQ: MDWD) and its U.S. commercial partner Vericel Corporation (NASDAQ: VCEL) today announced that the U.S. Biomedical Advanced Research and Development Authority (BARDA) within the Assistant Secretary for Preparedness and Response (ASPR), a part of the U.S. Department of Health and Human Services (HHS), has begun procuring NexoBrid® for emergency stockpile as part of the HHS mission to build national preparedness for public health medical emergencies. BARDA purchased inventory will be managed by MediWound under vendor managed inventory. The initial BARDA procurement is valued at $16.5 million, with the first delivery of NexoBrid expected by the end of the first quarter of 2020 and additional deliveries occurring over the subsequent five quarters. In addition, BARDA holds an option to procure additional quantities of NexoBrid through funding of up to $50 million. The submission of the Biologics License Application (BLA) for NexoBrid to the U.S. Food & Drug Administration (FDA) is planned for the second quarter of 2020.

"The initiation of the NexoBrid procurement by BARDA is a significant milestone in our partnership with BARDA," said MediWound Chief Executive Officer Sharon Malka. "We have been working with BARDA since 2015 on multiple development and training initiatives with the mutual goal of adding NexoBrid to ASPR's portfolio of medical countermeasures for mass casualty emergencies. The initiation of the procurement while NexoBrid is at the pre-BLA stage underscores the importance of NexoBrid to U.S. national preparedness for treatment of large number of severe thermal burns injuries."

"Our country faces a multitude of evolving threats that could result in an overwhelming number of people suffering from burn injuries," explained BARDA Director Rick Bright, Ph.D. "Today's purchase is part of our ongoing efforts to provide first responders and other medical professionals with fast access to the products they will need to save as many lives as possible. The progress of NexoBrid to date is a testament to how much can be accomplished in a relatively short time through public-private partnership."

"We believe that availability of NexoBrid for emergency response will significantly increase U.S. readiness for burn mass casualty incidents," said Nick Colangelo, President and Chief Executive Officer of Vericel. "The increasing number of burn centers enrolling in the NexoBrid expanded access treatment protocol will help ensure that major burn centers across the country are trained and experienced in the use of NexoBrid should such an event take place."

The procurement is a key milestone of the Project BioShield (PBS) contract signed in September 2015 between MediWound and BARDA. 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.

Recently, MediWound initiated the NexoBrid expanded access treatment protocol (NEXT), 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. MediWound has submitted documents for consideration by the FDA supporting the use of NexoBrid in a declared national medical emergency contingent upon the FDA issuance of an Emergency Use Authorization (EUA). 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.

At the end of July 2019, MediWound and Vericel participated in a pre-BLA meeting with the FDA and received concurrence that the existing safety and efficacy data including the two Phase 3 clinical studies and the twelve-month safety follow up data from DETECT are adequate to allow for BLA submission and review of NexoBrid. 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. The companies anticipate filling the BLA during the second quarter of 2020.

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 percent 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
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
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 submissions or 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; the ability to submit to FDA a BLA in the timeframe expected; 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. 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, 2018, 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, 2018, filed with the Securities and Exchange Commission ("SEC") on February 26, 2019, 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.

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