Vericel and MediWound Announce Initiation of U.S. NexoBrid Expanded Access Treatment Protocol

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CAMBRIDGE, Mass. and YAVNE, Israel, Oct. 02, 2019 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ: VCEL) and MediWound Ltd. (NASDAQ: MDWD) today announced initiation of the NexoBrid® expanded access treatment protocol (NEXT) to treat burn patients with deep partial- and full-thickness burns in the U.S. during the preparation and review of the NexoBrid Biologics License Application (BLA).

"We are excited to initiate NEXT in the U.S. in tandem with preparations with Vericel for the BLA filing," said Sharon Malka, MediWound's Chief Executive Officer. "NEXT, which is supported and funded by the Biomedical Advanced Research and Development Authority (BARDA), allows for the continued clinical use as well as non-declared emergency use of NexoBrid for U.S. patients prior to NexoBrid approval by the FDA. We believe NEXT will enhance national preparedness for burn mass casualty incidences, where it has the potential to meaningfully impact patients' lives."

Nick Colangelo, president and CEO of Vericel said, "After a successful pre-BLA meeting with the FDA, we remain on track for the BLA submission in the second quarter of 2020. NEXT will further extend the number of NexoBrid-trained physicians and healthcare providers in the U.S. and generate additional awareness, advocacy and use at U.S. burn centers prior to commercialization of NexoBrid."

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% 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 will participate. The increased number of burn centers trained and familiar with NexoBrid prior to FDA approval will improve national readiness for potential burn mass casualty events. To further promote national readiness, the FDA has agreed that in the event of a burn mass casualty event that is not a nationally declared emergency, additional patients could be treated under the NEXT treatment protocol.

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 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% 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, twelve-month long-term safety follow up data have been collected and are now being analyzed.

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 considered an investigational product in the United States. The companies anticipate filling the BLA in 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% 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), within the Office of the Assistant Secretary for Preparedness and Response in 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 this 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 US.

About FDA expanded access program

The U.S. Food and Drug Administration's (FDA) expanded access program allows access to investigational products to treat patients with serious or immediately life-threatening diseases or conditions outside of clinical trials when no comparable or satisfactory alternative treatment options are available.

Cautionary Note Regarding Forward-Looking Statements

This release includes forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, Section 21E of the US Securities Exchange Act of 1934, as amended, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other similar expressions. Forward-looking statements are statements that are not historical facts, and are based on Vericel's and MediWound's current knowledge and its present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several important factors, including but not limited to the ability to successfully develop and commercialize NexoBrid; the ability to submit to FDA a BLA in the timeframe expected; the ability to fund the development of NexoBrid until BLA submission; FDA may not accept part or all of the BLA; FDA may not provide marketing approval for NexoBrid in the United States; risks related to the timing and conduct of our NEXT; risks related to the contract with the U.S. Biomedical Advanced Research and Development Authority; the impact of government laws and regulations; and the additional risks discussed under the heading "Risk Factors" 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 SEC on February 26, 2019, Quarterly Reports on Form 10-Q and other filings with the SEC.

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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