BARDA to Fund NexoBrid Expanded Access Treatment Protocol for Thermal Burns

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NexoBrid Expanded Access Treatment Protocol (NEXT) to Start in the Third Quarter of 2019, Allowing for the Treatment of up to 150 Burn Patients at 30 Sites in the United States

CAMBRIDGE, Mass., May 29, 2019 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leader in advanced therapies for the sports medicine and severe burn care markets, today announced that the U.S. Biomedical Advanced Research and Development Authority (BARDA) has agreed to fund the NexoBrid® expanded access treatment (NEXT) protocol. The NEXT protocol is being conducted under the U.S. Food and Drug Administration's (FDA) expanded access program, which 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. U.S. burn surgeons participating in the NEXT protocol will be able to treat up to 150 patients during the preparation and review of the NexoBrid Biologics License Application (BLA).

On May 7, 2019, Vericel announced that it had entered into exclusive license and supply agreements with MediWound Ltd. to commercialize NexoBrid in North America. 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. MediWound will receive the additional funding from BARDA under an amendment to an existing BARDA contract. Under the terms of the License Agreement, MediWound will continue to conduct all development activities under the supervision of a Central Steering Committee comprised of members of each party until the BLA is approved and subsequently transferred to Vericel.

The NEXT protocol 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. Up to 30 sites will participate in the NEXT protocol. The protocol has been designed to be consistent with current real-life burn treatment practices in the U.S. The increased number of burn centers trained and familiar with NexoBrid prior to FDA approval and commercial availability 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.

"We are very pleased with BARDA's commitment to make NexoBrid available to patients under an expanded access protocol," said Nick Colangelo, president and CEO of Vericel. "It is a reflection of the significant need for improved burn treatments and the compelling body of clinical data supporting the use of NexoBrid. The NEXT protocol will further extend the number of NexoBrid-trained physicians and healthcare providers in the United States and generate additional awareness, advocacy, and use at U.S. centers of excellence prior to commercialization of NexoBrid."

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 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 support for development of NexoBrid has been provided by 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 and HHSO100201800023C.

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This document contains forward-looking statements, including, without limitation, statements concerning anticipated progress, objectives and expectations regarding the commercial potential of Vericel products, intended product development, clinical activity timing, regulatory process, and objectives and expectations regarding our company described herein, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "we believe," "targeted" and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "potential," "can continue," "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 timing and conduct of clinical trial and product development activities, timing of the commencement of the NEXT protocol, extension of NexoBrid use, timing or likelihood of regulatory submissions or approvals, availability of funding from BARDA, potential payments under the license and supply agreements, growth in revenue, profit and margins, impact to adjusted EBITDA, estimating the commercial potential of our products and product candidates, competitive developments, market demand for our products and product candidates, product performance, and our ability to supply or meet customer demand for our products. These and other significant factors are discussed in greater detail 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 filings with the SEC. These forward-looking statements reflect management's current views and Vericel does not undertake 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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