Vericel Provides Regulatory Update for NexoBrid

June 29, 2021

CAMBRIDGE, Mass., June 29, 2021 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leader in advanced therapies for the sports medicine and severe burn care markets, today announced that its development partner, MediWound Ltd., received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the Biologics License Application (BLA) for NexoBrid, a potential treatment for eschar removal in adults with deep partial-thickness and/or full-thickness burns.

The FDA communicated to MediWound that it had completed its review of the BLA, as amended, and has determined that it cannot approve the BLA in its present form. The FDA identified issues related to the Chemistry, Manufacturing and Controls (CMC) section of the BLA and requested that MediWound provide additional CMC information. The FDA stated that it has not reviewed several amendments submitted by MediWound in response to the CMC information requests for this action. The FDA also stated that inspections of manufacturing facilities in Israel and Taiwan are required before the BLA can be approved, but that it was unable to conduct the required inspections during the current review cycle due to COVID-related travel restrictions. In addition, the CRL referenced observations that were made during good clinical practice (GCP) inspections related to the DETECT study and requested that MediWound address questions regarding the impact of the observations on the study's efficacy findings. The FDA also requested that MediWound provide a safety update as part of its BLA resubmission.

"We are committed to working with MediWound and the FDA on next steps to address the issues identified in the complete response letter in order to obtain the potential approval of NexoBrid and bring this important product to patients as expeditiously as possible," said Nick Colangelo, President and CEO of Vericel. "Importantly, we will continue to support the NexoBrid expanded access treatment (NEXT) protocol during the resubmission and FDA review process."

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 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.

Forward Looking Statements
Vericel cautions 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 relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. Our 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.

Among the factors that could cause actual results to differ materially from those set forth in the forward-looking statements include, but are not limited to, uncertainties associated with the timing or likelihood of approval by the U.S. Food & Drug Administration of the NexoBrid BLA for treatment of severe burns in the United States or other North American markets, availability of funding from BARDA under its agreement with MediWound Ltd. for use in connection with NexoBrid development activities, and the wide-ranging impacts of the COVID-19 pandemic on our business or the economy generally.

With respect to FDA's review of the pending NexoBrid BLA, the COVID-19 pandemic may impact the FDA's response times to future regulatory submissions, its ability to monitor our clinical trials, and/or conduct necessary reviews or inspections of manufacturing facilities involved in the production of NexoBrid, any or all of which may result in timelines being materially delayed, which could affect the development and ultimate commercialization of NexoBrid. The total impact of these disruptions could have a material impact on the Company's financial condition, cash flows and results of operations.

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, 2020, filed with the Securities and Exchange Commission (SEC) on February 24, 2021, Vericel's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 5, 2021, and in other filings with the SEC. These forward-looking statements reflect our views as of the date hereof and Vericel does not assume and specifically disclaims 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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