Vericel Announces Submission of Biologics License Application to the FDA for NexoBrid for the Treatment of Severe Thermal Burns

June 30, 2020 at 7:00 AM EDT

CAMBRIDGE, Mass., June 30, 2020 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ: VCEL) today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking the approval of NexoBrid® (concentrate of proteolytic enzymes enriched in Bromelain) for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns. 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. Funding and technical support to MediWound Ltd. for development of NexoBrid is provided by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

The BLA submission for NexoBrid is based on multiple preclinical and clinical studies including the pivotal Phase 3 U.S. clinical study (DETECT) of NexoBrid in adult patients with deep partial-thickness and full-thickness thermal burns up to 30% of total body surface area. The study met its primary endpoint of complete eschar removal as well as all secondary endpoints, including shorter time to eschar removal, a lower incidence of surgical eschar removal, and lower blood loss during eschar removal compared to standard of care (SOC), including both surgical and non-surgical debridement methods. A key safety endpoint, non-inferiority in time to complete wound closure compared with patients treated with SOC, was also achieved. Long-term follow-up data to assess cosmesis, function, and quality of life, including 12-month results from the DETECT study, were also included in the submission.

"The BLA submission for NexoBrid marks an important milestone in our partnership with MediWound, bringing us one step closer to providing NexoBrid as an innovative treatment for the thousands of patients admitted to burn units each year with deep partial-thickness and full-thickness burns who would benefit from rapid and selective eschar removal," said Nick Colangelo, President and CEO of Vericel. "We look forward, together with MediWound, to working with the FDA during the BLA filing and review process as we seek marketing approval for NexoBrid in the United States."

Sharon Malka, CEO of MediWound added, "Submitting the NexoBrid BLA has been a team effort and we thank all of the investigators, their teams, our employees and all our partners, especially BARDA and Vericel, for their commitment to the program. This is a major milestone for MediWound and it is gratifying to know NexoBrid is one step closer to being available to help burn victims in the U.S."

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. 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.

Cautionary Note Regarding 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, all of which are difficult to predict and many of which are beyond our control. 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.

Specifically, this press release contains forward-looking statements concerning the anticipated progress, development, objectives, expectations and commercial potential of NexoBrid. Among the factors that may cause results to be materially different from those stated herein 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, including its commercial growth potential and the market demand for the product; 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 Study; 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. For example, we are unable to predict how the pandemic will affect the overall healthcare infrastructure, including the pace with which governmental agencies, such as the FDA, will review and approve regulatory submissions. Additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation efforts also may impact our ability to source supplies for our operations or our ability to sell and support the use of NexoBrid in the future.

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, 2019, filed with the Securities and Exchange Commission ("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 management's current views as of the date hereof and Vericel does not undertake, and specifically disclaims, any obligation to update any of these forward-looking statements to reflect a change in our views or events or circumstances that occur after the date of this release except as required by law.

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