Vericel Enters into Exclusive License Agreement with MediWound for North American Rights to NexoBrid, a Biological Orphan Product for Debridement of Severe Thermal Burns

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Pivotal U.S. Phase 3 Clinical Study Met Primary and All Secondary Endpoints

Highly Synergistic with Existing Commercial Franchise and Significantly Expands Vericel's Presence in the Severe Burn Care Market

CAMBRIDGE, Mass., May 07, 2019 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leader in advanced cell therapies for the sports medicine and severe burn care markets, today announced that it has 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. NexoBrid is approved in the European Union and other international markets and has been designated as an orphan biologic in the United States.

In January 2019, MediWound announced positive top-line results from 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 as well as all secondary endpoints, including shorter time to eschar removal, a lower incidence of surgical eschar removal, and lower blood loss compared to standard of care (SOC). A key safety endpoint, non-inferiority in time to complete wound closure compared with patients treated with SOC, was also achieved. Planned twelve-month and twenty-four month safety follow-ups are ongoing for cosmesis, function, quality of life and other safety measurements.

"We are delighted to expand our burn care franchise with the addition of NexoBrid, a highly innovative product with compelling clinical and pharmacoeconomic data that represents a paradigm shift in burn care for hospitalized patients," said Nick Colangelo, president and CEO of Vericel. "NexoBrid is an excellent strategic fit with our advanced therapy portfolio and is highly synergistic with our existing commercial franchise. The addition of NexoBrid significantly expands our target addressable market and supports a broader commercial footprint to both drive NexoBrid uptake and increase Epicel penetration as we broaden our focus to a significantly larger segment of hospitalized burn patients. We look forward to working closely with the MediWound team to bring NexoBrid to the U.S. market."

The U.S. Biomedical Advanced Research and Development Authority (BARDA) has awarded MediWound a contract valued at up to $132 million for the advancement of the development and manufacturing, as well as the procurement, of NexoBrid in the United States. Under the contract, BARDA provides technical assistance and $56 million in funding support towards NexoBrid development costs including the ongoing DETECT study and a Phase 3 pediatric (CIDS) study to obtain U.S. marketing approval from the Food and Drug Administration (FDA). The contract also includes a $16.5 million commitment for procurement of NexoBrid contingent upon FDA eligibility for use in an emergency or FDA marketing approval. The contract provides an option to fund up to $50 million for additional NexoBrid procurement. Independently, BARDA also awarded a different contract to MediWound for up to $43 million to support the development of NexoBrid as a debridement product to treat sulfur mustard injuries.

Under the terms of the license agreement, Vericel will make an upfront payment to MediWound of $17.5 million, with an additional $7.5 million payment contingent upon U.S. approval and up to $125 million contingent upon meeting certain annual sales milestones. The first sales milestone of $7.5 million would be triggered when NexoBrid annual net sales in North America exceed $75 million. Vericel also will pay MediWound tiered royalties on net sales ranging from single-digit to low double-digit percentages, and a percentage of gross profits on initial committed BARDA procurement orders and a royalty on any additional BARDA purchases of NexoBrid. Vericel also entered into a supply agreement with MediWound under which MediWound will manufacture NexoBrid for Vericel for a supply price of cost plus a fixed margin percentage.

"In addition to the clear strategic fit with our burn care franchise, this transaction is attractive from a financial perspective as well," said Nick Colangelo. "The performance-based deal structure, together with BARDA funding support for development expenses to obtain U.S. marketing approval and medical countermeasure procurement, makes the transaction essentially neutral to adjusted EBITDA in the near-term and generates longer-term margins consistent with expected margins for our current portfolio."

Approximately 40,000 burn patients are hospitalized in the U.S. each year[1], most of whom require the debridement of burn eschar to facilitate healing and reduce the risk of infection.[2] Surgical excision of eschar, or escharectomy, is currently standard of care and is performed through repeated use of a large surgical blade to remove necrotic tissue until bleeding, healthy tissue is reached.[2] While effective, surgical debridement is not selective, results in the loss of both viable tissue and blood, and requires general anesthesia for the patient and operating facilities for the burn center or hospital.[3] Currently available enzymatic debridement agents require a minimum of once daily application[4] with dressing changes over a number of days. NexoBrid enables the rapid and early removal of eschar while reducing patients' surgical burden and the related loss of blood and healthy tissue associated with escharectomy.[5]

"MediWound is excited to partner with Vericel, a company that shares our commitment to bringing innovative therapies to the market to meet the needs of burn patients," said Stephen T. Wills, Chairman of MediWound. "Vericel's proven track record of commercializing novel products and changing standard of care, as well as their strong history with the burn community, gives us confidence that they are the ideal partner to realize the full potential of NexoBrid in North America."

The U.S. Biologics License Application (BLA) currently is targeted for submission to the FDA in the fourth quarter of 2019 based on the acute primary, secondary and safety data, with the analysis of the twelve-month safety follow-up data submitted during the BLA review and the twenty-four month safety follow-up data submitted as a BLA supplement, subject to FDA concurrence at a pre-BLA meeting planned for the first half of 2019.

For more information on this transaction please refer to the Form 8-K filed today with the U.S Securities and Exchange Commission (SEC).

About Vericel Corporation
Vericel is a leader in advanced cell 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. 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. 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.

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 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, increasing market penetration for Epicel, 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.

References

1. American Burn Association - https://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/.
2. Plast Aesthet Res 2018;5:33.
3. Total Burn Care (Fifth Edition), 2018, Pages 131-157.
4. Santyl Prescribing Information.
5. Burns 43 (2017) 1640 – 1653; Annals of Burns and Fire Disasters - vol. XXVIII - n. 4 - December 2015; Burns 2014; 40: 466-474.

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