Vericel Announces U.S. Commercial Availability of NexoBrid® (anacaulase-bcdb) for the Treatment of Severe Thermal Burns in Adults

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Full commercial launch of NexoBrid marks important first step to becoming the new standard of care for eschar removal in patients with deep partial- and/or full- thickness thermal burns

NexoBrid launch significantly expands the total addressable market for Vericel Burn Care

CAMBRIDGE, Mass., Sept. 20, 2023 (GLOBE NEWSWIRE) -- Vericel Corporation (NASDAQ:VCEL), a leader in advanced therapies for the sports medicine and severe burn care markets, today announced the U.S. commercial availability of NexoBrid® (anacaulase-bcdb) for the removal of eschar in adults with deep partial- and/or full-thickness thermal burns.

Eschar removal is a critical first step in the treatment of burns as it can reduce inflammation, stop burn progression, as well as mitigate infections and sepsis. Surgical excision, which is the current standard of care for eschar removal, often results in the removal of viable tissue. NexoBrid selectively targets eschar while preserving viable tissue, enabling more rapid and precise eschar removal, which may reduce the need for subsequent skin grafting and lessen patient trauma.

“We are very pleased to announce the U.S. commercial availability of NexoBrid, as it significantly expands our Burn Care franchise and represents an important paradigm shift in the treatment of severe thermal burns,” said Nick Colangelo, President and CEO of Vericel. “In addition to providing burn surgeons with an important new tool to manage these severely injured patients, NexoBrid will also diversify our revenue stream and enhance our topline earnings.”

Each year, approximately 40,000 people are hospitalized in the U.S. for burn-related injuries, and of those patients, more than 30,000 of them require some level of eschar removal, representing a $300 million addressable market for NexoBrid. NexoBrid can be applied in up to two applications of four hours each. A first application of NexoBrid may be applied to an area of up to 15% body surface area. A second application of NexoBrid may be applied 24 hours later, with a total treated area for both applications of up to 20% Total Body Surface Area (TBSA).

About NexoBrid
NexoBrid (anacaulase-bcdb) is a botanical drug product containing proteolytic enzymes indicated for the removal of eschar in adults with deep partial- and/or full-thickness thermal burns. To learn more about NexoBrid, please visit www.NexoBrid-US.com.

Indication: NexoBrid (anacaulase-bcdb) is indicated for eschar removal in adults with deep partial-thickness and/or full-thickness thermal burns.
Limitations of Use
The safety and effectiveness of NexoBrid have not been established for treatment of:

- Chemical or electrical burns
- Burns on the face, perineum, or genitalia
- Burns on the feet of patients with diabetes mellitus or on the feet of patients with occlusive vascular disease
- Circumferential burns
- Burns in patients with significant cardiopulmonary disease, including inhalation injury

NexoBrid is not recommended for wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions with the product and an increased risk of spreading the noxious substance.

Important Safety Information

- **Contraindications**: NexoBrid is contraindicated in patients with: known hypersensitivity to anacaulase-bcdb, bromelain, pineapples, or to any other components; known hypersensitivity to papayas or papain because of the risk of cross-sensitivity.
- **Warnings and Precautions:**
  - **Hypersensitivity Reactions:** Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarketing use of anacaulase-bcdb.
  - **Pain Management:** Manage pain as appropriate for an extensive dressing change of burn wounds. At least 15 minutes prior to NexoBrid-related procedures ensure adequate pain control measures are in place.
  - **Proteolytic Injury to Non-Target Tissues:** NexoBrid is not recommended for treatment of burn wounds where medical devices or vital structures could become exposed during eschar removal.
  - **Coagulopathy:** Avoid use of NexoBrid in patients with uncontrolled disorders of coagulation. Use with caution in patients on anticoagulant therapy or other drugs affecting coagulation, and in patients with low platelet counts and increased risk of bleeding from other causes. Monitor patients for possible signs of coagulation abnormalities and signs of bleeding.
- **Adverse Reactions:** The most common adverse reactions (>10%) were pruritus and pyrexia.
- **Geriatric:** Clinical studies of NexoBrid did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

- To report negative side-effects, contact the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.
- For complete risk information, please see the **Full Prescribing Information**.

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 and one specialty biologic product 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® (anacaulase-bcdb), a biological orphan product containing proteolytic enzymes, which is indicated for the removal of eschar in adults with deep partial- and/or full-thickness burns. For more information, please visit 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 our expectations regarding future revenue, growth in revenue, market penetration for MACI, Epicel, and NexoBrid, growth in profit, gross margins and operating margins, the ability to continue to scale our manufacturing operations to meet the demand for our cell therapy products, including the timely completion of a new headquarters and manufacturing facility in Burlington, Massachusetts, the ability to achieve or sustain profitability, contributions to adjusted EBITDA, the expected target surgeon audience, potential fluctuations in sales and volumes and our results of operations over the course of the year, timing and conduct of clinical trial and product development activities, timing and likelihood of the FDA's potential approval of the arthroscopic delivery of MACI to the knee or the use of MACI to treat cartilage defects in the ankle, the estimate of the commercial growth potential of our products and product candidates, competitive developments, changes in third-party coverage and reimbursement, physician and burn center adoption of NexoBrid, supply chain disruptions or other events affecting MediWound Ltd.'s ability to manufacture and supply NexoBrid to meet customer demand, negative impacts on the global economy and capital markets resulting from the conflict in Ukraine, global geopolitical tensions or record inflation and potential future impacts of the COVID-19 pandemic on our business or the economy generally.

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, 2022, filed with the Securities and Exchange Commission (SEC) on February 23, 2023, Vericel's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the SEC on August 2, 2023, 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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