Vericel Announces FDA Approval of NexoBrid for the Treatment of Pediatric Patients with Severe Thermal Burns

August 15, 2024 at 4:05 PM EDT

Approval Expands NexoBrid Target Customer Base to Include Approximately 20 Pediatric Burn Centers

CAMBRIDGE, Mass., Aug. 15, 2024 (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. Food and Drug Administration (FDA) has approved a pediatric indication for NexoBrid® (anacaulase-bcdb) for eschar removal in pediatric patients with deep partial-thickness and/or full-thickness thermal burns.

“We are pleased that the FDA approved NexoBrid for pediatric use as it provides a novel non-surgical solution for managing severe burn injuries in this vulnerable pediatric patient population,” said Nick Colangelo, President and CEO of Vericel. “We believe NexoBrid is poised to become the new standard of care for eschar removal and make a meaningful impact on the lives of adult and pediatric burn patients, and we look forward to further executing on our NexoBrid commercial launch.”

The FDA approval of the pediatric indication for NexoBrid is based on the results of a global Phase 3 clinical trial, Children Innovation Debridement Study (CIDS), which evaluated the safety and efficacy of NexoBrid in hospitalized pediatric patients, as well as additional pediatric data available from Phase 3 and Phase 2 studies conducted during the clinical development of NexoBrid. Vericel is expanding its target customer base to include the approximately 20 pediatric burn centers in the United States, which the Company expects will have a meaningful impact on overall NexoBrid uptake over time.

“For pediatric burn patients, NexoBrid represents a less invasive alternative to traditional methods and the approval ensures that children will now have access to this innovative non-surgical option to quickly and effectively treat severe thermal burns,” said Steven Kahn, MD, Chief of Burn Surgery at MUSC, University Hospital and Shawn Jenkins Children’s Hospital.

NexoBrid was initially approved for eschar removal in adults with deep partial-thickness and/or full-thickness thermal burns by the FDA on December 28, 2022, and is commercially available in the United States.

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

Indications for Use: NexoBrid (anacaulase-bcdb) is indicated for eschar removal in adults and pediatric patients 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
- Treatment of burn wounds where medical devices (e.g., implants, pacemakers, shunts) or vital structures (e.g., large vessels) could become exposed during eschar removal

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 post-marketing use of anacaulase-bcdb. If a hypersensitivity reaction occurs, remove NexoBrid (if applicable) and initiate appropriate therapy. Healthcare personnel should take appropriate precautions to avoid exposure when preparing and handling NexoBrid (e.g., gloves, surgical masks, other protective coverings, as needed.)
  - **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 (>5%) in adults were pruritus, pyrexia, wound complication, anemia, vomiting and insomnia. The most common adverse reactions (>5%) in pediatric patients were pruritus, pyrexia and vomiting.
- **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 Vericel Corporation at 888-454-BURN (888-454-2876) or FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.
- Please see **Full Prescribing Information**.

About Vericel Corporation

Vericel is a leading provider of advanced therapies for the sports medicine and severe burn care markets. The Company combines innovations in biology with medical technologies, resulting in a highly differentiated portfolio of innovative cell therapies and specialty biologics that repair injuries and restore lives. Vericel markets three 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. Vericel also holds an exclusive license for North American rights to NexoBrid® (anacaulase-bcdb), a biological orphan product containing proteolytic enzymes, which is indicated for eschar removal in adults and pediatric patients with deep partial-thickness and/or full-thickness thermal burns. For more information, please visit www.vcel.com.

Epicel and MACI are registered trademarks of Vericel Corporation. NexoBrid is a registered trademark of MediWound Ltd. and is used under license to Vericel Corporation. © 2024 Vericel Corporation. All rights reserved.

Forward Looking Statements

This press release contains forward-looking statements. Forward-looking statements are subject to risks and uncertainties such as those described in Vericel's periodic reports on file with the Securities and Exchange Commission. 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 the market penetration for NexoBrid, physician and burn center adoption of NexoBrid, and supply chain disruptions or other events or factors affecting MediWound's ability to manufacture and supply sufficient quantities of NexoBrid to meet customer demand, including but not limited to the ongoing Israel-Hamas war. Actual results may differ materially from anticipated results.

Investor Contact:
Eric Burns
ir@vcel.com
+1 (734) 418-4411

Media Contact:
Julie Downs
media@vcel.com