



## MediWound Announces Positive Results from the U.S. NexoBrid® Expanded Access Protocol (NEXT)

August 5, 2024

### NEXT Confirms NexoBrid's Proven Safety and Efficacy in Eschar Removal, Significantly Reducing Surgical Procedures for Burn Patients

YAVNE, Israel, Aug. 05, 2024 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair, today announced the positive results of the NEXT—an Expanded Access Protocol. NEXT, initiated in 2019, aimed to ensure the continuous availability of NexoBrid® in burn centers until its commercialization. This program successfully maintained physician expertise, provided burn victims with ongoing access to this life-saving treatment, and facilitated the accumulation of real-world safety and clinical data for NexoBrid.

Jeremy Goverman, MD, FACS, Associate Professor of Surgery at Harvard Medical School, commented, "The NEXT results reaffirm the significant benefits of NexoBrid in managing severe burns. This enzymatic debridement agent accelerates the debridement process and reduces the need for surgical interventions, ultimately enhancing patient outcomes. The findings from NEXT are consistent with data from the DETECT and CIDS Phase III trials, reinforcing the critical role that NexoBrid should play in standard burn care protocols."

NEXT, an open-label, single-arm treatment protocol was conducted at 29 burn centers across the U.S. 239 patients, including 215 adults and 24 children, with deep partial and full-thickness thermal burns covering up to 30% of the total body surface area (TBSA) were treated with NexoBrid.

#### Key Results of the NEXT Protocol Include:

- **Efficacy** (findings were consistent with Phase III studies results):
  - 94.9% of adults and 100% of children achieved complete debridement.
  - Only 4.2% of adults required surgical excision for eschar removal after NexoBrid treatment, and none in the pediatric group.
  - The mean ( $\pm$  SD) percent of wound area surgically excised for adults was 3.6% ( $\pm$ 18.33), and 0% for children.
  - The time to complete eschar removal was less than one day for both adults and children.
- **Healing and Hospitalization:**
  - The median time to wound closure was 22 days (95% CI: 22, 23) for adults and 28 days (95% CI: 18, 32) for children.
  - The median time of hospitalization duration was 10 days (95% CI: 8, 11) for adults and 10 days (95% CI: 5, 14) for children.
- **Safety:** The safety data was consistent with the established safety profile of NexoBrid, and no new safety concerns were identified by the Data Safety and Monitoring Board (DSMB).
- **Benefit-Risk Ratio:** The overall benefit-to-risk ratio of NexoBrid treatment remains favorable.

#### About NexoBrid

NexoBrid® is a topically administered biological product that enzymatically removes nonviable burn tissue, or eschar, in patients with deep partial and/or full-thickness thermal burns without harming viable tissue. NexoBrid® is approved in over 40 countries, including the United States, European Union, and Japan. It has been designated as an orphan biologic drug in all these territories.

NexoBrid development has been supported in whole or in part with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract HHSO100201500035C. This contract provided funding and technical support for the pivotal U.S. Phase 3 clinical study (DETECT), the randomized, controlled pivotal clinical trial for use in the pediatric population (CIDS), the marketing approval registration process for NexoBrid as well as its procurement and availability under the expanded access protocol (NEXT). Additional projects for evaluation of NexoBrid funded under the BARDA contract include establishment of a pre-emergency use data package and development of the health economic model to evaluate the cost savings impact to enable market adoption in the United States.

#### About MediWound

MediWound Ltd. (Nasdaq: MDWD) is the global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. The Company specializes in the development, production and commercialization of rapid and effective biologics that improve existing standards of care and patient experiences, while reducing costs and unnecessary surgeries.

MediWound's first drug, NexoBrid®, is an FDA and EMA-approved orphan biologic for eschar removal in deep partial-thickness and/or full-thickness thermal burns, which can significantly reduce surgical interventions. Utilizing the same core biotherapeutic enzymatic platform technology, MediWound

has developed a strong R&D pipeline, including the company's lead drug under development, EscharEx<sup>®</sup>. EscharEx is a Phase III-ready biologic for the debridement of chronic wounds, offering significant potential advantages over the dominant \$360+ million product and an opportunity to expand the market.

For more information visit [www.mediwound.com](http://www.mediwound.com) and follow the Company on [LinkedIn](#).

### **Cautionary Note Regarding Forward-Looking Statements**

*MediWound 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, expectations and commercial potential of our products and product candidates, including NexoBrid<sup>®</sup>. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated our expectations regarding future growth, market acceptance of our products and product candidates; our ability to maintain adequate protection of our intellectual property; competition risks; the impact of government laws and regulations and the impact of the current global macroeconomic climate on our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of our products and product candidates in the future. These and other significant factors are discussed in greater detail in MediWound's annual report on Form 20-F for the year ended December 31, 2023, filed with the Securities and Exchange Commission ("SEC") on March 21, 2024 and Quarterly Reports on Form 6-K and other filings with the SEC from time-to-time. These forward-looking statements reflect MediWound's current views as of the date hereof and MediWound undertakes, and specifically disclaims, any obligation to update any of these forward-looking statements to reflect a change in their respective views or events or circumstances that occur after the date of this release except as required by law.*

### **MediWound Contacts:**

Hani Luxenburg  
Chief Financial Officer  
MediWound Ltd.  
[ir@mediwound.com](mailto:ir@mediwound.com)

Daniel Ferry  
Managing Director  
LifeSci Advisors, LLC  
[daniel@lifesciadvisors.com](mailto:daniel@lifesciadvisors.com)

### **Media Contact:**

Ellie Hanson  
FINN Partners for MediWound  
[ellie.hanson@finnpartners.com](mailto:ellie.hanson@finnpartners.com)  
+1-929-588-2008