MediWound Announces Phase III CIDS Publication on NexoBrid® for Pediatric Burn Care

February 25, 2025

Findings in Burns Journal confirm NexoBrid's superiority over standard of care in pediatric patients with deep thermal burns
NexoBrid is approved for pediatric use in the U.S., E.U. and Japan

YAVNE, Israel, Feb. 25, 2025 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a global leader in next-generation enzymatic therapeutics for tissue repair, today announced the publication of its Phase III Children Innovative Debridement Study (CIDS) in *Burns*, the peer-reviewed Journal of the International Society for Burn Injuries *(ISBI).* The study evaluated the efficacy and safety of NexoBrid® compared to the standard of care (SOC) in pediatric patients with deep partial- and full-thickness thermal burns. Read the full publication here.

The publication, titled *"Open-Label RCT of the Efficacy and Safety of NexoBrid Compared to SOC in Children with Burns,"* presents findings that supported the label expansion of NexoBrid for pediatric patients in the E.U. (2023) and U.S. (2024). These results reinforce NexoBrid's clinical benefits as a rapid, effective, and non-surgical alternative for eschar removal in pediatric burn patients, validating its significance as a transformative treatment in burn care.

"Pediatric burn patients account for approximately 30% of all burn cases, and their treatment presents unique challenges. Surgical procedures can be particularly traumatic for young patients, making non-surgical alternatives essential" said Professor Jose Ramón Martínez-Méndez, Head of Burns Unit, University Hospital La Paz, Madrid, Spain. "NexoBrid provides a rapid, non-surgical solution that effectively removes eschar while preserving healthy tissue, addressing the critical need to protect viable dermis and improve outcomes for pediatric burn patients."

About the CIDS Phase III

The CIDS Phase III was a multicenter, multinational, randomized, controlled, open label study, conducted in pediatric patients with deep partial thickness (DPT) and full thickness (FT) thermal burns across 36 burn centers in the US, EU, Israel and India. The study randomized 145 pediatric patients, ranging from newborn to eighteen years of age, randomized 1:1 to receive either NexoBrid or SOC.

Key Findings:
All co-primary endpoints were successfully met:

1. Faster eschar removal: NexoBrid achieved complete eschar removal in a median time of one day compared to six days with SOC ($p < 0.001$)
2. Reduced wound area excised: The mean percentage of wound area surgically excised was significantly lower in the NexoBrid arm vs. SOC (1.5% vs. 48.1%, respectively, $p < 0.001$)
3. Comparable long-term outcomes: At 12 months, NexoBrid demonstrated comparable cosmesis and functional outcomes to SOC, with lower (better) MVSS scores of 3.8 in the NexoBrid arm vs. 4.9 in the SOC (test for non-inferiority, $p < 0.001$)

Additional findings:

4. Reduced need for surgery: 8.3% of NexoBrid treated patients required surgical excision vs. 64.4% of patients treated with SOC ($p < 0.001$)
5. High efficacy: 94.2% of patients treated with NexoBrid achieved complete eschar removal
6. Comparable safety profile: NexoBrid demonstrated comparable safety profile to SOC

About NexoBrid

NexoBrid® is a topically administered biological orphan drug that enzymatically removes eschar while preserving viable tissue in patients with deep partial- and full-thickness thermal burns. It is approved for use in in more than 40 countries, including the United States, European Union, and Japan.

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 treatment 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 a global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. The Company specializes in the development, production and commercialization of innovative biologics that enhance existing standards of care and improve patient experiences while reducing healthcare 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, significantly reducing the need for surgical interventions. Leveraging its proprietary enzymatic technology, MediWound is advancing EscharEx®, a promising candidate currently in Phase III development for the debridement of chronic wounds. Phase II clinical trials have shown EscharEx has distinct advantages over the currently available $375+ million drug for wound debridement, presenting a unique opportunity for significant market growth.

For more information visit www.mediwound.com and follow us 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, study design, expected data timing, objectives anticipated timelines, expectations and commercial potential of NexoBrid and EscharEx®. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the uncertain, lengthy and expensive nature of the product development process; the timing and conduct of our studies of EscharEx, including the timing, progress and results of current and future clinical studies, and our research and development programs; the approval of regulatory submission by the FDA, the European Medicines Agency or by any other regulatory authority, our ability to obtain marketing approval of EscharEx in the U.S. or other markets; the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of our products and products; our expectations regarding future growth, including our ability to develop new products; market acceptance of NexoBrid and EscharEx; our ability to maintain adequate protection of our intellectual property; competition risks; the need for additional financing; 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.

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