MediWound Announces U.S. Food and Drug Administration Approval of NexoBrid® for the Treatment of Pediatric Patients with Severe Thermal Burns

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Approval Helps Solidify NexoBrid's Position in the U.S. as a Safe and Effective Non-Surgical Burn Treatment for All Ages

YAVNE, Israel, Aug. 15, 2024 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair, today announced that the U.S. Food and Drug Administration (FDA) has approved a pediatric indication for NexoBrid® (anacaulase-bcdb) allowing for eschar removal in pediatric patients aged newborn through eighteen with deep partial- and/or full-thickness thermal burns. With this FDA approval, NexoBrid is now authorized for use in the U.S. for all age groups, aligning with its approvals in the European Union and Japan.

"Today's announcement marks a significant milestone in our mission to improve burn care with NexoBrid," said Ofer Gonen, Chief Executive Officer of MediWound. "Pediatric burn victims represent over 30% of the total burn population, and the current surgical standard of care can be extremely traumatic for both patients and their families. Since NexoBrid's initial approval, we have been dedicated to expanding its use to children, reflecting our long-term commitment to revolutionizing burn care."

The submission was supported by the results of a global Phase III 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 III and Phase II studies conducted during the clinical development of NexoBrid. Of note, the CIDS trial was funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services.

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 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 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 ®. 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 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, study design, expected data timing, objectives anticipated timelines, expectations and commercial potential of our products and product candidates, including NexoBrid. 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 our products and product candidates, 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 our products and product candidates 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 our products and product candidates; 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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