MediWound Announces U.S. Commercial Availability of NexoBrid® for the Treatment of Severe Thermal Burns in Adults

September 21, 2023

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

YAVNE, Israel, Sept. 21, 2023 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation enzymatic therapeutics for tissue repair, 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 thrilled to announce that NexoBrid is now commercially available in the United States through our partner, Vericel," stated Ofer Gonen, Chief Executive Officer of MediWound. "This pivotal milestone underscores our commitment to providing burn patients with immediate access to cutting-edge treatments and furthering our mission to minimize the need for surgical interventions."

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 in the U.S. 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 (TBSA). A second application of NexoBrid may be applied 24 hours later, with a total treated area for both applications of up to 20% TBSA.

About NexoBrid

NexoBrid® (anacaulase-bcdb) 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 in United States, European Union and Japan, where it has been designated as an orphan biologic drug. Development of NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

About MediWound Ltd.

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

MediWound's first drug, NexoBrid ®, is an FDA-approved orphan biologic for eschar removal in severe burns that can replace surgical interventions and minimize associated costs and complications. 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 debridement of chronic wounds with significant advantages over the $300 million monopoly legacy drug and an opportunity to expand the market. MediWound's pipeline also includes MW005, a topical therapeutic for the treatment of basal cell carcinoma that has demonstrated positive results in a recently completed Phase I/II study.

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; risks related to our contracts with BARDA; 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, 2022, filed with the Securities and Exchange Commission ("SEC") on March 16, 2023 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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