MediWound Announces that FDA has Accepted for Review the Supplement to the NexoBrid BLA to Include Pediatric Patients with Severe Thermal Burns

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If approved, NexoBrid will serve as an effective non-surgical treatment for both pediatric and adult burn patients in the U.S.

NexoBrid is already approved for use for burn patients across all age groups in Europe and Japan

YAVNE, Israel, Jan. 09, 2024 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully integrated biopharmaceutical company focused on next-generation enzymatic therapeutics for tissue repair, today announced that the U.S. Food and Drug Administration (FDA) has completed their filing review and accepted a supplement to the NexoBrid® biologics license application (sBLA) for the removal of eschar in pediatric patients with deep partial- and/or full-thickness thermal burns.

NexoBrid, a topically administered biological drug that enzymatically removes nonviable burn tissue, received FDA approval in the U.S. in December 2022 for eschar removal in adult patients with deep partial-thickness and/or full-thickness thermal burns.

The sBLA seeks to expand the label for NexoBrid to include both adult and pediatric burn patients of all ages. It 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. 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.

"The acceptance of the NexoBrid sBLA filing by the FDA marks an important milestone for MediWound and reinforces our commitment to redefine the standard of care for the treatment of severe burns across all age groups," said Ofer Gonen, CEO of MediWound. "NexoBrid is already approved for the adult and pediatric populations in Europe and Japan, and we look forward to working with the FDA, alongside our partner Vericel, throughout the sBLA review process."

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 in United States, European Union and Japan, where it has been designated as an orphan biologic drug.

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) in the U.S. 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. 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 potential advantages over the $360 million dominant 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, 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 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, 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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