



## MediWound Completes Enrollment Stage of its NexoBrid Phase 3 Pediatric Study

October 28, 2020

### Top-line Data is Expected in the Second Half of 2021

YAVNE, Israel, Oct. 28, 2020 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, today announced it has completed the enrollment stage of its NexoBrid® Phase 3 pediatric clinical study (CIDS - Children Innovation Debridement Study). Top-line results with 12 months follow up data anticipated during the second half of 2021. Additionally, the completion of the CIDS enrollment stage follows the U.S. Food and Drug Administration (FDA)'s recent agreement to allow the NexoBrid expanded access (NEXT) protocol to be expanded to include pediatric as well as adult burn patients.

"We are pleased to complete the enrollment stage of our NexoBrid pediatric Phase 3 study, which is one of the most comprehensive randomized controlled studies ever conducted in pediatric burn patients," said Sharon Malka, Chief Executive Officer of MediWound. "The current mode of pediatric burn management requires intensive medical therapy, which poses challenges due to the surgical complexities in treating young patients with severe burns. Having NexoBrid as a non-surgical option, provides a minimally invasive alternative to the current surgical standard of care for treating severe burns in pediatric patients. We look forward to generating top-line results while we expand enrollment in our ongoing NEXT protocol to also include pediatric patients."

Nick Colangelo, President and CEO of Vericel added, "Completing the enrollment stage of the CIDS study is an important step toward our goal of providing NexoBrid as a treatment option for pediatric patients with severe burns given NexoBrid's potential to address the unique challenges in treating children with severe burns."

CIDS is a Phase 3, multicenter, multinational, prospective, controlled, assessor-blinded study with 145 patients aged 0-18 years, randomized to be treated with either NexoBrid or standard-of-care, with follow-up periods at 12 months and at 24 months. The study's objectives are to evaluate the efficacy and safety of NexoBrid compared with the standard-of-care in hospitalized children with severe thermal burns of 1 percent to 30 percent Total Body Surface Area (TBSA). The study is being conducted primarily in the U.S. and Europe in accordance with a design and study protocol endorsed by both the European Medicines Agency (EMA) and the U.S. FDA. The study design includes two stages of data analysis – upon 12-month data collection, anticipated in the second half of 2021, and upon 24-month data collection, anticipated in the second half of 2022. The study is fully funded by the Biomedical Advance Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS).

The ongoing NEXT protocol, which is supported and funded by BARDA, enables the continued clinical use of NexoBrid for U.S. patients during the review of the NexoBrid Biologics License Application (BLA). NEXT is an open-label, single-arm treatment protocol which allows for the treatment of up to 150 burn patients with deep partial and full-thickness thermal burns up to 30 percent of total body surface area. NEXT has been designed to be consistent with current real-life burn treatment practices in the U.S. and up to 30 U.S. burn centers are anticipated to participate.

The inclusion of pediatric patients in the NEXT protocol will allow additional physicians to expand their experience with NexoBrid in pediatric patients, ensure burn care preparedness, and expand the national capacity of trained physicians available to treat patients with NexoBrid in a non-declared emergency until the potential approval of the product for pediatric use in the U.S.

### About NexoBrid

NexoBrid (concentrate of proteolytic enzymes enriched in Bromelain) is a topically administered biological product that enzymatically removes nonviable burn tissue, or eschar, in patients with deep partial and full-thickness thermal burns within four hours of application without harming viable tissue. NexoBrid is approved in the European Union and other international markets and has been designated as an orphan biologic drug in the United States, European Union, and other international markets. Vericel holds an exclusive license for North American commercial rights to NexoBrid. In January 2019, MediWound announced positive top-line results from the acute phase of the pivotal Phase 3 U.S. clinical study (DETECT) of NexoBrid in adult patients with deep partial-and full-thickness thermal burns up to 30 percent of total body surface area. The study met its primary endpoint of complete eschar removal compared to gel vehicle as well as all secondary endpoints compared to standard of care (SOC), including shorter time to eschar removal, a lower incidence of surgical eschar removal and lower blood loss during eschar removal. Safety endpoints, including the key safety endpoint of non-inferiority in time to complete wound closure compared with patients treated with SOC, were also achieved. In addition, the twelve-month follow-up safety data of cosmesis and function were found to be comparable between the treatment and SOC arms, and no new safety signals were observed. On September 16, 2020, the FDA accepted for review the NexoBrid BLA for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns and assigned a Prescription Drug User Fee Act (PDUFA) target

date of June 29, 2021. Additional twenty-four-month long term safety follow up data will be submitted as a safety labeling update as part of a post-approval commitment. NexoBrid is currently an investigational product in the United States.

### **About MediWound Ltd.**

MediWound is a fully-integrated biopharmaceutical company focused on developing, manufacturing and commercializing novel therapeutics based on its patented proteolytic enzyme technology to address unmet needs in the fields of severe burns, chronic and other hard-to-heal wounds. MediWound's first innovative biopharmaceutical product, NexoBrid, non-surgically and rapidly removes burn eschar without harming viable tissue. The product has received marketing authorization from the European Medicines Agency as well as the Israeli, Argentinian, South Korean, Russian and Peruvian Ministries of Health for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns. On June 29, 2020, a biological license application (BLA) was submitted to the U.S. FDA. MediWound's second innovative product, EscharEx<sup>®</sup> is a topical biological drug candidate for the debridement of chronic and other hard-to-heal wounds using the same proteolytic enzyme technology as NexoBrid. In two Phase 2 studies, EscharEx has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a few daily applications. For more information, please visit [www.mediwound.com](http://www.mediwound.com).

### **About BARDA**

Funding and technical support for development of NexoBrid including the expanded access treatment protocol (NEXT), the pivotal Phase 3 pediatric clinical study (CIDS) and the marketing approval registration process for NexoBrid in the U.S. is provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. HHSO100201500035C. Additional projects for evaluation of NexoBrid funded under the BARDA contract include randomized, controlled pivotal clinical trial for use in adults population, 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. For more information, refer to [www.phe.gov/about/BARDA](http://www.phe.gov/about/BARDA).

### **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, objectives, expectations, and commercial potential of NexoBrid. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the timing and conduct of clinical trial and product development activities; the timing or likelihood of regulatory approvals; timeline of the 12- and 24-month data; the ability to successfully develop and commercialize NexoBrid, including its commercial growth potential and the market demand for the product; the availability of funding from BARDA under its agreement with MediWound for use in connection with NexoBrid development activities; competitive developments; whether FDA will provide marketing approval for NexoBrid in the United States; the risks related to the timing and conduct of NEXT Study, including the enrollment of pediatric patients; the impact of applicable laws and regulations; and the uncertainties associated with the scope, scale and duration of the impact of the COVID-19 pandemic.*

*Specifically, the pandemic may impact the FDA's response times to regulatory submissions, its ability to monitor our clinical trials, and/or conduct necessary reviews or inspections any or all of which may result in timelines being materially delayed, which could affect the development and ultimate commercialization of NexoBrid. Additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation efforts also may impact our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of NexoBrid 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, 2019, filed with the Securities and Exchange Commission ("SEC") on February 25, 2020, 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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