MediWound Announces Additional $9 Million in Funding from BARDA to Support NexoBrid BLA Resubmission and the Expanded Access Treatment Protocol

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YAVNE, Israel, Feb. 10, 2022 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced that the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, has expanded its awarded contract with MediWound by providing supplemental funding of $9 million to support the NexoBrid® BLA resubmission with the U.S. Food and Drug Administration (FDA) and the ongoing expanded access treatment protocol (NEXT).

"We are greatly appreciative that BARDA is providing additional funds to develop NexoBrid, and support NexoBrid's potential approval to enhance U.S. preparedness," said Sharon Malka, CEO of MediWound. "We look forward to continuing our long-lasting collaboration with BARDA and our U.S. commercial partner Vericel in order to make NexoBrid available to U.S. burn patients, as we continue to advance the preparation of the BLA resubmission anticipated in mid-2022."

MediWound was awarded its first BARDA contract for treatment of thermal burn injuries in 2015. That first BARDA contract, valued at up to $168 million, supported advanced development and manufacturing, as well as the procurement of NexoBrid as a medical countermeasure as part of U.S. preparedness for mass casualty events. Under that first BARDA contract, BARDA provided technical assistance and a total of up to $91 million for NexoBrid development activities needed to request U.S. marketing approval from the FDA. These activities include the NexoBrid Phase 3 (DETECT) study and subsequent requirements for BLA resubmission, the ongoing Phase 3 pediatric (CIDS) study and the NexoBrid expanded access treatment protocol (NEXT). In January 2020, BARDA committed an additional $16.5 million to procure NexoBrid as part of the HHS mission to build national preparedness for public health medical emergencies. The contract further includes a $10 million option to fund development of other potential NexoBrid indications, and an option to procure additional NexoBrid valued at up to $50 million.

In addition to that first BARDA contract, BARDA also has a separate contract with MediWound to support the development of NexoBrid as a debridement product to treat sulfur mustard injuries (chemical burns).

The cumulative, non-dilutive funding under both contracts with BARDA is now valued at up to $211 million. As of December 31, 2021, the company has received approximately $70 million in funding, in the aggregate, from BARDA under the two contracts to support development activities and an additional $14.6 million for procurement of NexoBrid for U.S. emergency preparedness.

NexoBrid development has been supported in part with federal funding from BARDA, Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract numbers HHSO100201500035C and HHSO100201800023C.

Contract number HHSO100201500035C provides funding and technical support including the expanded access treatment protocol (NEXT), the pivotal U.S. Phase 3 clinical study (DETECT) and the marketing approval registration process for NexoBrid in the U.S. Additional projects for evaluation of NexoBrid funded under the BARDA contract include randomized, controlled pivotal clinical trial for use in pediatric 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.

About MediWound Ltd.
MediWound is a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, bio-therapeutic solutions for tissue repair and regeneration. Our strategy leverages our enzymatic technology platform, focused on next-generation bioactive therapies for burn care, wound care and tissue repair.

NexoBrid®, our commercial orphan biological product for non-surgical eschar removal of deep-partial and full-thickness thermal burns, is a bromelain-based biological product containing a sterile mixture of proteolytic enzymes that selectively removes burn eschar within four hours without harming surrounding viable tissue. NexoBrid is currently marketed in the European Union and other international markets and is at registration-stage in the U.S. NexoBrid is supported by the Biomedical Advanced Research and Development Authority (BARDA), office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services.

EscharEx®, our next-generation bioactive topical therapeutic under development in the U.S. for debridement of chronic and hard to heal wounds. In two Phase 2 studies, EscharEx was well-tolerated and has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a few daily applications.

MW005, our topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development.

Committed to innovation, we are dedicated to improving quality of care and patient lives. For more information, please visit www.mediwound.com.

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 topline 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; our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets; risks related to our contracts with BARDA; 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 COVID-19 pandemic. For example, we are unable to predict how the pandemic will affect the overall healthcare infrastructure, including the ability to recruit patients, the ability to conduct the studies in medical sites and the pace with which governmental agencies, such as the FDA, will review and approve regulatory submissions. 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 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, 2020, filed with the Securities and Exchange Commission ("SEC") on February 25, 2021, 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 statments 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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