MediWound Announces an Additional $10 Million Award from BARDA

May 9, 2023

Funding to support emergency stockpiling replenishment, pediatric indication submission, and expanded access treatment protocol extension

YAVNE, Israel, May 09, 2023 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation enzymatic therapeutics for tissue repair, today announced that 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 (HHS), has awarded an additional $10 million to MediWound. The supplemental funding will support a $3 million replenishment of expired product previously procured for emergency preparedness, the pediatric indication sBLA submission to the U.S. Food and Drug Administration (FDA), and enrollment of an additional 50 patients in the ongoing expanded access treatment protocol (NEXT).

"Our long-standing partnership with BARDA has been instrumental in NexoBrid's successful development. We are thrilled at the prospect of making it available in the U.S. market," said Ofer Gonen, Chief Executive Officer of MediWound. "Replenishment of the NexoBrid emergency stockpile highlights the critical importance of the product and ensures that in the event of a mass casualty burn incident, patients in the U.S. will have access to this lifesaving agent in a timely manner. We remain committed to advancing innovative solutions that will meet medical needs and improve patient outcomes."

The NexoBrid® indication expansion will include treatment of pediatric burn victims, which comprises more than 30% of the total burn population. NexoBrid is particularly relevant to the pediatric population as the current surgical standard of care (SOC) is extremely traumatic. NexoBrid enables clinicians to provide a safe, fast, and highly effective non-surgical debridement option that addresses the unmet need in the pediatric population.

The NEXT protocol provides for continued access to NexoBrid for up to 250 patients (in both the pediatric and adult populations), while maintaining physician skills until NexoBrid is commercially available in the U.S. for adults, and prior to receiving FDA approval for the pediatric indication.

MediWound was awarded its first BARDA contract for treatment of thermal burn injuries in 2015. This contract, now valued at up to $175 million, supported advanced development and manufacturing, as well as the procurement of NexoBrid as a medical countermeasure as part of U.S. emergency preparedness for a mass casualty. Under that contract, BARDA provided technical assistance and a total of up to $98 million for NexoBrid development activities required for U.S. marketing approval from the FDA. These activities include the NexoBrid Phase 3 study (DETECT) and subsequent BLA resubmission requirements, the pediatric Phase 3 study (CIDS), 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 $47 million.

This project has been supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number HHSO100201500035C.

BARDA also has a separate contract of up to $41 million to support MediWound in the development of NexoBrid as a debridement agent for sulfur mustard cutaneous burns in both pediatric and adult indications.

The cumulative, non-dilutive funding under both contracts with BARDA is now valued at up to $216 million. As of December 31, 2022, the company has received approximately $82 million, in aggregate, from BARDA under the two contracts to support development activities and an additional $16.5 million for procurement of NexoBrid for U.S. emergency preparedness.

About MediWound Ltd.
MediWound Ltd. (Nasdaq: MDWD), a biopharmaceutical company, is the global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. With a 20+ year history 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 ®, an FDA-approved orphan biologic for eschar removal in severe burns, can replace the current standard of care which is costly surgical interventions, while minimizing the complications associated with them. Utilizing the same biotherapeutic enzymatic platform technology, MediWound has developed a strong R&D pipeline. This includes the Company's primary focus product under development, EscharEx®. EscharEx is a Phase III biologic for debridement of chronic wounds, with

significant advantages over the $300+mm monopoly legacy drug and an opportunity to expand the market. The Phase III study is expected to start in Q4 2023. Additionally, the company has a Phase I/II biologic for basal cell carcinoma, MW005, with results expected in Q3 of 2023.

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 use of funds received from BARDA, the exercise of the replenishment option anticipated progress, development, study design, expected data timing, objectives anticipated timelines, expectations and commercial potential of our products and product candidates including NexoBrid® and EscharEx®. 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 prospectus supplement, the 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, 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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