BARDA Upsizes its Contract with MediWound Awarding an Additional $5.5 Million for Emergency Readiness for NexoBrid Deployment

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Total non-dilutive funds for NexoBrid now valued at over $200 million

YAVNE, Israel, March 03, 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 that the U.S. Biomedical Advanced Research and Development Authority (BARDA) has expanded its awarded contract with MediWound providing supplemental funding of $5.5 million to support emergency readiness for NexoBrid deployment upon request of use of NexoBrid in mass casualty situation.

"BARDA's expanded commitment is further validation of NexoBrid's importance to U.S. national preparedness for treatment of large number of severe thermal burns injuries. We greatly appreciate BARDA's continued support and contribution over the years to the development of NexoBrid," said Sharon Malka, CEO of MediWound. "We have started to build a NexoBrid emergency stockpile and designing processes for emergency deployment upon request of use of NexoBrid in mass casualty situation. In addition, the increasing number of burn centers enrolling into the NexoBrid expanded access treatment (NEXT) protocol will ensure that major burn centers across the U.S. are trained and experienced in the use of NexoBrid should such an event take place. In parallel, we continue to advance the preparation of the BLA and anticipating submission to the FDA in mid-year and subject to approval, commercial launch by our partner Vericel in 2021."

Under the modified contract including this supplemental amount, BARDA will provide technical assistance and a total of $82 million in funding for NexoBrid development activities towards U.S. marketing approval from the Food and Drug Administration (FDA). The additional $5.5 million of supplemental funding is to support emergency readiness for a potential deployment of NexoBrid upon request of use in mass casualty situation, following the initiation of NexoBrid procurement for emergency stockpile as part of the U.S. Department of Health and Human Services (HHS) mission to build national preparedness for public health medical emergencies. This modified contract maintains a $10 million option to fund development of other potential NexoBrid indications, and an option to fund up to $50 million for additional NexoBrid procurement. In addition to this modified contract, BARDA also has a separate independent contract with MediWound to support the development of NexoBrid as a debridement product to treat sulfur mustard injuries. This contract provides $12 million in funding to support research and development activities up to pivotal studies in animals with options for additional funding of up to $31 million for additional development activities through BLA submission.

The cumulative non-dilutive funding under both contracts with BARDA is now valued at up to $202 million. As of December 31, 2019 the Company has received approximately $43 million from BARDA.

About BARDA
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, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies and diagnostic tools for public health medical emergencies. For more information, refer to www.phe.gov/about/BARDA.

Funding and technical support for development of NexoBrid 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. 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 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 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. MediWound's second innovative product, EscharEx® 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.

Cautionary Note Regarding Forward-Looking Statements

This release includes forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, Section 21E of the US Securities Exchange Act of 1934, as amended, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, such as statements regarding assumptions and results related to timing of regulatory filings and submissions; expected funding from BARDA and/or exercise of its options; our ability to meet the timeline for the initiation of the NEXT treatment protocol, results of the NEXT treatment protocol and Vericel's ability to commercialize NexoBrid.. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other similar expressions. Forward-looking statements are based on MediWound's current knowledge and its present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. In particular, you should consider that we may not submit the BLA to FDA in the timeframe expected, or at all; we will not continue to receive funding under BARDA contract or BARDA may choose not to exercise its options, we meet the timeline for the initiation of the NEXT study FDA may not provide marketing approval for NexoBrid in the United States and, if such approval is obtained, Vericel may not be able to successfully commercialize NexoBrid in the United States; and the risks discussed under the heading "Risk Factors" in our annual report on Form 20-F for the year ended December 31, 2019 as well as information contained in other documents filed with or furnished to the Securities and Exchange Commission. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that future results, levels of activity, performance and events and circumstances reflected in the forward-looking statements will be achieved or will occur. The forward-looking statements made herein speak only as of the date of this announcement and MediWound undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law.

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