



BARDA Upsizes Support for NexoBrid with an Additional \$21 Million to Fund Continuous Access Treatment Protocol for Thermal Burn

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Total non-dilutive funds for NexoBrid now valued at up to \$196 Million

MediWound to initiate NexoBrid expanded access treatment protocol (NEXT) in the third quarter of 2019, allowing for ongoing use of NexoBrid to treat burn patients in U.S.

YAVNE, Israel, May 29, 2019 (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 upsize its awarded contract with MediWound and provided supplemental funding of \$21 million to initiate NexoBrid expanded access treatment protocol (NEXT).

Under the modified contract including this supplemental amount, BARDA will provide technical assistance and a total amount of \$77 million in funding for NexoBrid development activities towards U.S. marketing approval from the Food and Drug Administration (FDA). These activities include the ongoing NexoBrid Phase 3 (DETECT) study and subsequent requirements for Biologics License Application (BLA) submission, the ongoing Phase 3 pediatric (CIDS) study and now also the new NexoBrid expanded access treatment protocol. The modified contract maintains the \$16.5 million commitment for procurement of NexoBrid, contingent upon FDA eligibility for use in an emergency or marketing approval; 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 with MediWound for treatment of thermal burn injuries, BARDA also has a separate independent contract with MediWound to support the development of NexoBrid as a debridement product to treat sulfur mustard injuries, providing \$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. As a result of the additional \$21 million in committed funds for the thermal burn contract, the total non-dilutive funding under both contracts with BARDA is now valued at up to \$196 million. As of March 31, 2019 the Company has received approximately \$31 million from BARDA.

"We are very pleased with BARDA's continued commitment towards the development of NexoBrid, allocating supplemental funds to support multiple indications. BARDA's continuous support underscores its endorsement of our breakthrough therapy for treatment of severe burns and its mission for building mass casualty event preparedness," said Sharon Malka, CEO of MediWound. "BARDA's significant continuous support and our recently announced commercial agreement with Vericel for rights within North America further validate NexoBrid's role as an important treatment for patients with severe burns. We look forward to continuing our collaboration with BARDA and Vericel in order to make NexoBrid available to U.S. burn patients."

The NEXT protocol allows for the treatment of up to 150 burn patients, suffering from deep, partial and full thickness burns, covering up to 30% total body surface area. The NEXT as an open-label, single-arm treatment protocol, would expand the access to allow multiple burn centers across the U.S. to further evaluate NexoBrid in patients prior to its FDA approval and commercial availability in the U.S. The NEXT protocol has been designed to be consistent with the current U.S. real-life burn-care practice, enabling MediWound to increase the number of burn centers trained in the use of NexoBrid across the U.S., and thereby furthering the national preparedness for burn mass casualty incidences. Additionally, the FDA agreed that in a burn mass casualty that is not a nationally declared emergency, patients could be treated under the NEXT treatment protocol. MediWound has established procedures which would allow collection of data on clinical performance outcomes and safety.

Mr. Malka added, "We plan to initiate the NEXT expanded access treatment protocol in the third quarter of 2019, in tandem with our preparation of the NexoBrid BLA, which is planned for submission in the fourth quarter of this year, subject to FDA concurrence. The NEXT protocol allows for the continued clinical use as well as non-declared emergency use of NexoBrid on U.S. patients, prior to NexoBrid approval by the FDA. We believe the NEXT treatment protocol will further extend the NexoBrid user-base across the U.S. and generate further awareness, advocacy, and use at U.S. centers of excellence, potentially facilitating significant market penetration".

About BARDA

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in 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 support for development of NexoBrid has been provided by 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 and HHSO100201800023C.

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, received marketing authorization from the European Medicines Agency as well as the Israeli, Argentinian, South Korean and Russian Ministries of Health, for removal of dead or damaged tissue, known as eschar, in adults with deep partial and full-thickness thermal burns. NexoBrid represents a new paradigm in burn care management, and clinical trials have demonstrated, with statistical significance, its ability to non-surgically and rapidly remove the eschar earlier and without harming viable tissues.

MediWound's second innovative product, EscharEx[®] is a topical biological drug being developed for debridement of chronic and other hard-to-heal wounds. EscharEx is complementary to the many existing wound healing products, which require a clean wound bed in order to heal the wound.

EscharEx contains the same proteolytic enzyme technology as NexoBrid, and benefits from the wealth of existing development data on NexoBrid. In two Phase 2 studies, EscharEx demonstrated safety and efficacy in the debridement of 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, 2018 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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