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BARDA Gives Notice of Intent to Exercise First Contract Option to Further Fund MediWound's NexoBrid® Development

YAVNE, Israel, June 23, 2017 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq:MDWD), a fully-integrated biopharmaceutical company specializing in innovative therapies to address unmet needs in severe burn and wound management, announces that it received from the U.S. Biomedical Advanced Research and Development Authority (BARDA) a written Notice of Intent to exercise an option to fund further research and development (R&D) activities for expanding NexoBrid's indications.

The BARDA contract advances the development and manufacturing, as well as the procurement of NexoBrid, MediWound's proprietary pharmaceutical product for enzymatic removal of eschar in deep-partial and full-thickness thermal burns, as a medical countermeasure for preparedness for mass casualty events.

The five-year base contract signed in September 2015 includes $24 million to support U.S. Food and Drug Administration (FDA) approval of NexoBrid for use in thermal burn injuries as well as $16 million for procurement of NexoBrid, which is contingent upon FDA Emergency Use Authorization (EUA) and/or FDA marketing authorization for NexoBrid. In addition, the contract includes options for up to $22 million for expanding NexoBrid's indications for which the Company received the Notice of Intent and an option of up to $50 million for additional procurement. The total non-dilutive funding to MediWound under the BARDA contract is up to $112 million.

"BARDA has been a supportive development partner of NexoBrid in the U.S. for the past 20 months. Their expressed intent to fund further development efforts to expand NexoBrid's indications underscores their commitment to NexoBrid, as well as its potential in the treatment of severe burns and in building preparedness for mass casualty events," stated Gal Cohen, President and Chief Executive Officer of MediWound . "We look forward to continuing to work in collaboration with BARDA in order to bring NexoBrid to market to benefit severe burn victims."

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.

About Emergency Use Authorization (EUA)

The Emergency Use Authorization (EUA) allows the FDA to help strengthen public health protections in the United States against chemical, biological, radiological, and nuclear (CBRN) threats by facilitating the availability and use of medical countermeasures needed during public health emergencies. Under the Federal Food, Drug, and Cosmetic Act, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

About NexoBrid

NexoBrid is an easy-to-use, topically-applied product that removes dead or damaged tissue, known as eschar, in approximately four hours without harming the surrounding healthy tissues. NexoBrid received marketing authorization from the European Medicines Agency for the removal of eschar in adults with deep partial and full-thickness thermal burns, and is commercially available in Europe, Israel, and Argentina. Representing a new paradigm in burn care management, NexoBrid demonstrated in clinical studies, with statistical significance, its ability to non-surgically and rapidly remove the eschar earlier than other modalities, without harming viable tissues. The removal of eschar or "debridement" is a critical first step in the successful healing of severe burns as well as chronic and other hard-to-heal wounds. With the current standard of care, burn eschar is removed either with existing topical agents that have been found to be minimally effective or that take a significantly longer period of time to work, or by resorting to non-selective surgery, which is traumatic and may result in loss of blood and viable tissue necessitating further surgical treatments. The U.S. phase 3 clinical trial and registration process for NexoBrid is being funded in whole or in part with federal funds under a contract with the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority.

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, connective tissue disorders and other indications. MediWound's first innovative biopharmaceutical product, NexoBrid®, received marketing authorization from the European Medicines Agency as well as the Israeli and Argentinian Ministries of Health, for the removal of dead or damaged tissue, known as eschar, in adults with deep partial- and full-thickness thermal burns and was launched in Europe, Israel, and Argentina. 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, relative to the existing standard of care, without harming viable tissues.

MediWound's second innovative product candidate, EscharEx®, is a topical biological drug being developed for debridement of chronic and other hard-to-heal wounds and is complementary to the large number of 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 existing development data on NexoBrid®. In January 2017, MediWound reported final results from its second phase 2 study evaluating EscharEx for the debridement of chronic and other hard-to-heal wounds. In this phase 2 clinical trial, EscharEx met its primary endpoint demonstrating higher incidence of complete debridement with statistical significance. 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 U.S. 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 MediWound's expectations regarding BARDA's intent to exercise its option and its continued funding for research and development and procurement; the adequacy of BARDA funding to support NexoBrid® development efforts; the potential exercise of BARDA's option to further increase funding for development and/or BARDA's option for additional procurement, the potential role NexoBrid® may play in mass casualty events; the potential of NexoBrid® to be a new paradigm in burn care management, MediWound's ability to leverage existing data for the development of EscharEx®, and MediWound's expectations for the clinical development of both NexoBrid® and EscharEx®, including its expectations for regulatory approval. 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 the risks discussed under the heading "Risk Factors" in MediWound's annual report on Form 20-F for the year ended December 31, 2016 and information contained in other documents filed with the U.S. 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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