



July 19, 2017

## **BARDA Upsizes Contract with MediWound and Exercises Option to Fund Further NexoBrid® Indications**

### **Commits an Additional \$32 Million to Support R&D Activities, Brings Total Non-Dilutive Funding to Up to \$132 Million**

YAVNE, Israel, July 19, 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 the U.S. Biomedical Advanced Research and Development Authority (BARDA) has upsized its awarded contract with MediWound and exercised an option to fund further research and development (R&D) activities relating to NexoBrid®.

Under the modified signed contract, BARDA increased its committed funds to support NexoBrid R&D activities by \$32 million to approximately \$56 million, up from the original \$24 million. BARDA maintains an additional option to further fund \$10 million in development activities for other potential NexoBrid indications. The contract also maintains BARDA's \$16 million commitment for procurement of NexoBrid, which is contingent upon the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and/or FDA marketing authorization for NexoBrid, as well as BARDA's \$50 million option for additional procurement of NexoBrid. As a result of the exercise of BARDA's option, total non-dilutive funding to MediWound under the BARDA contract is now valued at up to \$132 million.

The BARDA contract serves to advance 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 upsized BARDA contract will fund the previously committed development activities to support the submission of a Biologic License Application to the FDA for NexoBrid for the use in thermal burn injuries. In addition, BARDA will now fund the Company's ongoing pediatric phase 3 study and its planned expansion to include U.S. pediatric burn care sites, as well as additional NexoBrid development efforts.

"The current management of pediatric burns requires intensive medical therapy and typically several traumatic surgical procedures to remove eschar and prevent secondary complications. In addition, burn surgery in pediatric patients is more demanding than in adults for a variety of reasons and can become a major bottleneck in the management of a mass casualty event," stated Prof. Lior Rosenberg, M.D., Chief Medical Technology Officer of MediWound, former Chief of Plastic Surgery at Soroka University Medical Center (Beer Sheva, Israel) and former Chairman of the Disaster Committee of the International Society for Burn Injuries. "BARDA's exercise of its option demonstrates its recognition of NexoBrid's potential to alleviate the unique challenges in treating children with severe burns, and we are pleased to have its continued support of our efforts to expand the use of NexoBrid to the pediatric population."

"In our recent meeting with the FDA, the FDA recognized the unmet need for safe and effective treatments for pediatric patients and agreed on the importance of including U.S. pediatric patients in our NexoBrid pediatric phase 3 program. This non-dilutive funding by BARDA, totaling up to \$132 million, provides significant support for our clinical development and manufacturing programs. We submitted the pediatric phase 3 protocol to the FDA with the goal of enrolling U.S. pediatric burn patients into our ongoing pediatric phase 3 study, which is underway in Europe," stated Gal Cohen, President and Chief Executive Officer of MediWound.

#### **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](http://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<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup> contains the same proteolytic enzyme technology as NexoBrid<sup>®</sup>, and benefits from existing development data on NexoBrid<sup>®</sup>. 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 study, EscharEx met its primary endpoint demonstrating higher incidence of complete debridement with statistical significance. For more information, please visit [www.mediwound.com](http://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 the continued BARDA funding for research and development and procurement; the adequacy of the BARDA funding to support NexoBrid<sup>®</sup> development efforts; the potential exercise of BARDA's additional option to further increase funding for development and/or BARDA's option for additional procurement, the potential role NexoBrid<sup>®</sup> may play in mass casualty events; the potential of NexoBrid<sup>®</sup> to be a new paradigm in burn care management, MediWound's ability to leverage existing data for the development of EscharEx<sup>®</sup>, and MediWound's expectations for the clinical development of both NexoBrid<sup>®</sup> and EscharEx<sup>®</sup>, 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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