

# MediWound Awarded Additional BARDA Contract Valued Up to \$43 Million for Development of NexoBrid® for Sulfur Mustard Injuries

September 24, 2018

YAVNE, Israel, Sept. 24, 2018 (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 awarded MediWound a new contract to develop NexoBrid<sup>®</sup> for the treatment of Sulfur Mustard injuries as part of BARDA preparedness for mass casualty events. Sulfur Mustard is a chemical warfare agent, typically dispersed as a fine mist of liquid droplets that causes thermal burns and skin injuries.

The contract provides approximately \$12 million of funding to support research and development activities up to pivotal studies in animals under the U.S. Food and Drug Administration (FDA) Animal Rule. The up to eight-year contract also contains options for additional funding of up to \$31 million for additional development activities, animal pivotal studies, and the FDA Biologics License Application (BLA) submission for approval of NexoBrid for the treatment of Sulfur Mustard injuries.

"We are pleased to have the endorsement of our technology by an additional department in BARDA and look forward to collaborating with BARDA on the development of NexoBrid for this new indication as part of the U.S. efforts to prepare for mass casualty events. Ten decades of research has not yet produced an approved treatment for Sulfur Mustard skin injury. Based on promising data from animal studies presented at the 2017 European Burn Association conference, NexoBrid has the unique potential to help victims of mass casualty events involving this chemical warfare agent, who otherwise would have to undergo radical surgical removal of contaminated skin," stated Gal Cohen, President and Chief Executive Officer of MediWound.

"Earlier this year, the FDA agreed that the development of this drug falls under the Animal Rule, as it is neither ethical nor feasible to conduct human trials with chemical warfare agents. Under the Animal Rule, the FDA may grant marketing approval based on adequate and well-controlled animal efficacy studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans," continued Mr. Cohen. "Now with the non-dilutive funding awarded by BARDA, we can move forward with animal trials in an effort to develop a non-surgical treatment option for Sulfur Mustard 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.

The project is being funded in whole with Federal funds from the Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. 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 <sup>®</sup>, 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 <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 and without harming viable tissues.

MediWound's second innovative product, 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 the wealth of existing development data on NexoBrid<sup>®</sup>. In two Phase 2 studies, EscharEx<sup>®</sup> has 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 the regulatory authorizations and launch dates. 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 our annual report on Form 20-F for the year ended December 31, 2017 and 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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