



## MediWound Expands Its NexoBrid® Phase 3 Children Innovation Debridement Study (CIDS) to the U.S.

June 19, 2018

*Study fully funded by BARDA*

YAVNE, Israel, June 19, 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 the expansion of its NexoBrid Phase 3 Children Innovation Debridement Study (CIDS) to United States burn centers, following approval of the study protocol by the U.S. Food and Drug Administration (FDA) and site Institutional Review Boards (IRB).

"We are very pleased to initiate enrollment of our CIDS Phase 3 study in the U.S., providing the opportunity to U.S. burn experts to treat pediatric patients with NexoBrid," said Gal Cohen, President and Chief Executive Officer of MediWound. "The current management of pediatric burns requires intensive medical therapy and typically several traumatic surgical procedures to remove eschar and prevent secondary complications. Burn surgery in pediatric patients is very demanding for a variety of reasons, such as complex anesthesia, thinner skin leaving narrow safety margins for surgical intervention, less skin graft donor site area and difficulties to diagnose burn severity early in scalding burns that are frequent in children. Published clinical results to date have demonstrated the merits of using NexoBrid as a non-surgical means to manage and treat these young patients including earlier eschar removal, reduced incidence and extent of surgical excision, grafting and blood loss. Our team is highly motivated to bring NexoBrid treatment to these young, vulnerable patients and this study expansion bring us one step closer to that goal," added Mr. Cohen.

### **About CIDS**

CIDS is a Phase 3, multicenter, multinational, randomized, controlled, open-label study in children with thermal burns. The study objectives are to evaluate the efficacy and safety of NexoBrid compared with the standard-of-care in hospitalized children with severe thermal burns of 1% to 30% Total Body Surface Area. The study is currently enrolling in Europe in accordance with a design endorsed by the European Medicines Agency (EMA) and is now being expanded to the U.S. after the Food and Drug Administration (FDA) endorsed the study protocol. Based on the recommendation of the study's Data Safety Monitoring Board (DSMB), after blindly reviewing the accumulated CIDS data, and the EMA and FDA endorsement, the study is now in its second stage with inclusion of younger pediatric burn patients beginning at the minimum age of one year. The study is fully funded through support from the Biomedical Advance Research and Development Authority (BARDA).

### **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 and South Korean 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 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 the wealth of existing development data on NexoBrid®. In two Phase 2 studies, EscharEx® 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](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 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.

### **Contacts:**

Sharon Malka	Bob Yedid
Chief Financial and Operations Officer	Managing Director

MediWound Ltd.  
[ir@mediwound.co.il](mailto:ir@mediwound.co.il)

LifeSci Advisors  
[bob@lifesciadvisors.com](mailto:bob@lifesciadvisors.com)  
646-597-6989



Source: MediWound Ltd.