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MediWound Initiates Second Stage of European Pediatric Phase 3 Study of NexoBrid® Expanding Treatment of Severe Burns to Children Age One to Four

New age bracket represents largest incidence of pediatric burns

YAVNE, Israel, Feb. 06, 2017 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq:MDWD), a fully integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, announces that the European Medicines Agency (EMA) has endorsed the extension of the Children Innovative Debridement Study (CIDS) population to include patients age one to 18. Based on the recommendation of the study's Data Safety Monitoring Board (DSMB), after blindly reviewing the accumulated CIDS data, and the EMA endorsement, MediWound will initiate the second stage of the study that allows inclusion of younger pediatric burn patients beginning at the minimum age of one instead of four years of age.

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 treatment with NexoBrid compared with standard of care (SOC) in hospitalized children with severe thermal burns of 1% to 30% total body surface area (TBSA). The study is underway in Europe in accordance with a study design endorsed by the EMA as part of the agreed Pediatric Investigational Plan to support extension of the indication to pediatric patients. The study includes three pre-defined stages: Stage 1 includes patients from age four to 18; Stage 2 includes patients from age one to 18; and Stage 3 includes patients from birth to age 18.

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. Pediatric anesthesia is difficult due to limited vascular access, small blood and fluid volumes, proneness to respiratory tract problems and acute heat loss and narrow safety margins of all anesthetic parameters. Children's thinner skin and smaller structures leave narrow safety margins for surgical intervention so excisional debridement often results in sacrificing the entire skin thickness and even harm to underlying structures. The smaller body surface offers less skin graft donor site area to cover the surgically excised eschar. Moreover, pediatric subjects tend to suffer from scalding burns that are not easily diagnosed, which further delays definitive treatment.

"We are very pleased to have EMA's endorsement to expand our EU CIDS Phase 3 study and include pediatric burn patients from age one to four as this age bracket represents the largest incidence of pediatric burns. Given the unique challenges of pediatric burn surgery and management, we believe that effective non-surgical eschar removal using an agent that does not harm viable dermis will facilitate early informed treatment decisions and reduce the surgical burden in such delicate patients," said Gal Cohen, Chief Executive Officer of MediWound.

"Nearly 100 children have already been treated in completed clinical studies of NexoBrid. NexoBrid has demonstrated multiple clinical benefits including earlier eschar removal, reduced number and extent of surgical excision, reduced incidence of grafting and autografted area, reduction in eschar-removal-related blood loss with no deleterious effect on time to wound closure, and showed comparable long-term cosmesis and function scores. In addition, the overall safety profile of pediatric patients treated with NexoBrid did not indicate any specific safety concern and was similar to that of adult patients.

"We look forward to further advancing the study in pediatric burn patients as there is an unmet need for a minimal invasive approach that will facilitate care. Our clinical results to date support the use of NexoBrid as a non-surgical means to manage and treat these challenging patients," added Mr. Cohen.

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, as well as chronic and other hard-to-heal wounds. MediWound's first innovative biopharmaceutical product, NexoBrid, received marketing authorization from the European Medicines Agency for removal of dead or damaged tissue, known as eschar, in adults with deep partial- and full-thickness thermal burns and has been launched in Europe. 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, a large and growing market. EscharEx[®] 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[®]. 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, 2015 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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