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Favorable Results from NexoBrid Phase 2 Pharmacokinetic Clinical Study Support Treatment of Severe Burns Covering up to 30% of Total Body Surface Area

YAVNE, Israel, Feb. 09, 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 positive results from a phase 2 study that evaluated the safety, pharmacokinetics (transcutaneous absorption) and efficacy of NexoBrid in hospitalized children and adults with severe thermal burns.

The multicenter, open-label, single-arm study was conducted in Europe, Israel and India and included 36 patients with severe burns of 4% to 30% total body surface area (TBSA). NexoBrid was applied to burns of up to 15% TBSA in one session, and when the wound area to be treated was more than 15% TBSA, NexoBrid was applied in two separate sessions, each up to 15% TBSA. Trial results showed that the use of NexoBrid was safe and effective. Furthermore, the pharmacokinetic profile following NexoBrid's first and second topical application was comparable, suggesting no concern with accumulation following a second topical application of NexoBrid.

Surgical excision of large surfaces of eschar results in substantial surgical burden on these very severe patients and involves massive blood loss. Surgery is often limited by the availability of the extensive donor site required, or by patient conditions that might not withstand general anesthesia or the significant burden of surgical debridement of such large surface areas.

"These PK data support the use of NexoBrid in larger TBSA burns, where the early non-surgical removal of eschar has many potential benefits as a large mass of contaminated eschar residing on the patient for longer periods of time can result in wound deterioration, infections, scars and other sequelae," noted Gal Cohen, Chief Executive Officer of MediWound. "In cases of large TBSA burns, being able to remove the eschar earlier and non-surgically may offer patients and physicians a real breakthrough in the treatment of these extensive and severe burns."

"Following discussions with the FDA, we amended the protocol for our U.S. Phase 3 DETECT study of NexoBrid to increase patient eligibility from 15% to 30% TBSA. As this study is also a post-approval commitment for European regulators, we obtained the European Medicines Agency's endorsement for the increase in TBSA in the DETECT study. We are very pleased with the results of the completed PK study and intend to use the data from this study as well as the PK data in large burns obtained from the on-going DETECT study to support a request to FDA and EMA to extend the label for NexoBrid to larger burns," concluded 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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