February 2, 2016

MediWound's EscharEx® Meets Primary Endpoint in Second Phase 2 Clinical Trial for the Debridement of Chronic and Hard-to-Heal Wounds

Data demonstrate strong results in diabetic foot ulcers and venous leg ulcers

Conference call with MediWound management and key opinion leader begins February 3, 2016 at 8:30 a.m. Eastern time

YAVNE, Israel, Feb. 02, 2016 (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 top-line results from the Company's second Phase 2 clinical trial evaluating EscharEx® for debridement of dead or damaged tissue in chronic and other hard-to-heal wounds.

EscharEx is based on the same propriety proteolytic enzyme technology used in MediWound's NexoBrid®, which is approved and commercially available in Europe and Israel for the removal of eschar in adults with deep partial- and full-thickness thermal burns. Effective debridement is a critical first step to facilitate wound management and is complementary to existing wound healing products, which require a clean wound bed.

Phase 2 Trial Objectives and Design

This trial was the second Phase 2 trial with EscharEx, following a feasibility Phase 2 trial, conducted in Israel with 24 patients that demonstrated the ability of EscharEx to debride chronic and hard-to-heal wounds of various etiologies.

The objectives of this second Phase 2 trial were to evaluate the efficacy of EscharEx in debriding chronic wounds, to assess its safety and lack of deleterious effect on wound healing and to further analyze these effects in different etiologies to guide the design of future pivotal studies.

This prospective, randomized, controlled, assessor-blinded Phase 2 trial of 73 patients was conducted at 15 clinical sites in Israel and Europe, and evaluated the safety and efficacy of EscharEx compared with hydrogel vehicle in a variety of chronic and hard-to-heal wounds including a study group of diabetic foot ulcers (DFUs), a study group of venous legs ulcers (VLUs) and a study group of post-surgical or traumatic hard-to-heal wounds. Patients were randomized to either EscharEx or the hydrogel vehicle at a ratio of 2:1, respectively.

The single, statistically-powered primary endpoint of the trial was incidence of complete debridement (non-viable tissue removal) at the end of the debridement period (up to 10 treatment days). Secondary endpoints assessed several parameters including time to debridement, wound healing and other efficacy and safety parameters. In addition, the trial included subgroup analyses for each etiology.

Primary Endpoint

The study met its primary endpoint with statistical significance. Patients treated with EscharEx demonstrated a higher incidence of complete debridement compared with patients treated with the hydrogel vehicle (EscharEx: 55% (27/49) vs. vehicle: 29% (7/24), p=0.047).

Predefined sub-group analyses showed that 50% of patients with DFUs treated with EscharEx (8/16) achieved complete debridement compared with 14% of patients with DFUs treated with hydrogel vehicle (1/7). In addition, 63% of patients with VLUs treated with EscharEx (10/16) achieved complete debridement compared with 25% of patients with VLUs treated with hydrogel vehicle (2/8).

Secondary Endpoints

The study included secondary endpoints that provide further insight on a number of efficacy and safety parameters.

The secondary endpoint of time to complete debridement demonstrated a clear trend (p=0.075) that strongly suggests that not only is there a difference in the incidence of debridement, as confirmed by the primary endpoint, but that debridement occurred earlier in the group treated by EscharEx.

The overall patient and wound demographics were comparable across both arms. No deleterious effect on wound healing was observed and no material differences were found in reported adverse events. The overall safety was comparable between the arms.

The planned three-month follow-up is ongoing and the Company expects the analysis of the complete dataset to be finalized in mid-2016.

The Company plans to submit the final data to the U.S. Food and Drug Administration (FDA) in the second half of 2016 and to request an end-of-Phase 2 meeting with the Agency thereafter.

Investigator and Management Commentary

"These data reinforce our belief that EscharEx has the potential to become a first-in-class topical debridement pharmaceutical product for the treatment of chronic wounds. There is a great unmet medical need to effectively debride chronic wounds in a non-surgical and prompt manner, as debriding the wound is a critical first step for consequent wound management," stated Prof. Josef Haik, M.D., Acting Manager of the Division of Plastic and Reconstructive Surgery and the National Intensive Care Burn Center, Sheba Medical Center, Israel and an investigator in the study. "Many patients with chronic wounds are elderly and/or have a number of co-morbidities, making them poor candidates for invasive sharp debridement. I look forward to the availability of EscharEx as it holds great potential to be a welcome addition to our treatment armamentarium for chronic wounds."

"The top-line data from this Phase 2 trial are highly encouraging. We conducted this trial to demonstrate EscharEx debridement efficacy in chronic wounds, to evaluate its safety and to determine the best indications to move forward in our clinical development program. We are delighted to report that we achieved all three of our goals," stated Gal Cohen, Chief Executive Officer of MediWound. "The only topical enzymatic debridement agent currently on the U.S. market requires daily application for several weeks to achieve complete debridement. Post-hoc analysis showed that 93% of the patients who completed debridement with EscharEx were debrided within seven days after four to five applications, on average.

"We recently completed a comprehensive market research study on EscharEx involving more than 200 healthcare professionals in the U.S. and Europe. According to the study, there are over 1.3 million patients with diabetic foot or venous leg ulcers in the U.S. alone who undergo debridement every year. The surveyed physicians indicated that a product having a profile such as EscharEx would potentially be prescribed to a significant portion of this patient pool. With an average cost of treatment of $1,000 to $2,000 per patient, EscharEx represents a significant market opportunity.

"In line with the results of this market research, we conducted a post-hoc analysis of patients treated in the trial with DFUs and VLUs. That analysis showed statistically significant improvements in both the incidence of complete debridement and the time to complete debridement in the EscharEx treated group. Based on the safety data and the compelling clinical activity EscharEx demonstrated in DFUs and VLUs, we are moving forward with our clinical program to make EscharEx available for treatment of these important indications.

"We extend gratitude to the investigators and their patients, who participated in this study," concluded Mr. Cohen.

Conference Call

MediWound management along with a clinical trial investigator will host a conference call for members of the investment community February 3, 2016 at 8:30 a.m. Eastern time to discuss these results and answer questions. Shareholders and other interested parties may participate in the call by dialing (877) 280-2296 (domestic) or (1809) 212-923 (Israel) and entering passcode 8689475. The call also will be broadcast live on the Internet on the Company's website at www.mediwound.com.

A replay will be available beginning two hours after the completion of the live call through February 9, 2016 by dialing (866) 932-5017 (domestic) or (800) 358-7735 (Israel) and entering passcode 8689475. The call will also be archived for 90 days on the Company's website at www.mediwound.com.

About Chronic and Other Hard-to-Heal Wounds and Eschar

Chronic and other hard-to-heal wounds are caused by impairment in the biochemical and cellular healing processes due to local or systemic conditions, and generally can take several weeks or longer to heal.

In each of the various wound types, the presence of the eschar is a frequent cause of wound chronification and the removal of eschar is a key step to commence healing. If not effectively treated, these wounds can lead to severe complications

including further infection, osteomyelitis, fasciitis, amputation and increased mortality. MediWound believes that most advanced wound care therapies would be complementary to EscharEx, as these therapies require a clean wound bed to effectively heal a wound.

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. 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.

Contacts:
Sharon Malka
Chief Financial & Operations Officer
MediWound Ltd.
ir@mediwound.co.il

Anne Marie Fields
Senior Vice President
LHA
212-838-3777
afields@lhai.com

Primary Logo

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