

MediWound Reports Final Positive Results of Phase 2 Clinical Trial of EscharEx for the Debridement of Chronic and Hard-to-Heal Wounds

Data support previously reported positive top-line results; No significant safety concerns observed in the follow-up period

YAVNE, Israel, Jan. 31, 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 final positive 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, which includes data from the follow-up period of six months from last treatment or three months from wound closure.

EscharEx is based on the same propriety proteolytic enzyme technology used in MediWound's NexoBrid[®], which is approved and commercially available in Europe, Israel and Argentina 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.

Study Design

The 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 vehicle¹ 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. EscharEx was applied to wounds once-daily for up to 10 consecutive daily applications, followed by 12 weeks of wound healing by standard of care and a follow up period in both arms.

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.

The objectives of the study were to (1) evaluate the efficacy of EscharEx in debriding chronic wounds, (2) to assess its safety and lack of deleterious effect on wound healing and (3) to further analyze these effects in different etiologies to guide the design of future pivotal studies. All three objectives were achieved.

¹ Hydrogel is not a true sham placebo as it is a common and widely used treatment for the debridement of chronic wounds.

Study Results

Based on the Final Clinical Study Report, the Phase 2 trial met its statistically-powered primary endpoint, the incidence of complete debridement at the end of the debridement period. Patients treated with EscharEx demonstrated a higher incidence of complete debridement (55% or 27/49) compared with patients treated with the hydrogel vehicle (29% or 7/24) with $p=0.047$.

Predefined sub-group analyses showed that 50% of patients with DFUs treated with EscharEx (8/16) achieved complete debridement at the end of the debridement period 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 at the end of the debridement period compared with 25% of patients with VLUs treated with hydrogel vehicle (2/8). Post-hoc analysis showed that 56.3% of patients with DFU or VLU in the EscharEx group had complete debridement at the end of the debridement period compared with 20.0% in hydrogel vehicle group ($p=0.028$).

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 advantage in time to complete debridement was corroborated by the statistically significant post hoc result in the subgroup of patients with DFUs or VLU that were treated with EscharEx ($p=0.024$).

Post hoc analysis shows that of patients that achieved complete debridement in the EscharEx group, 93% (25/27) completed the debridement within 7 daily applications (4-5 applications on average).

The overall patient 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.

These favorable results were achieved despite the fact that the average wound age in the EscharEx group was more than double that of the hydrogel vehicle group (72.8 weeks vs. 30.8 weeks) and the average wound size was larger in the EscharEx group (33.6 cm²) vs. the hydrogel vehicle group (25.8 cm²).

The Company will share these final data with the U.S. Food and Drug Administration (FDA) as part of its submitted request for a meeting with the Agency to discuss a U.S. pivotal clinical program for EscharEx.

Management Commentary

"We completed the study follow-up period and are happy to reaffirm the previously reported positive results. These final results reinforce our belief that EscharEx has the potential to become a first-in-class topical debridement treatment for chronic wounds," stated Gal Cohen, Chief Executive Officer of MediWound.

"As reported previously, following the successful completion of this first cohort of the Phase 2 study, we initiated a second cohort of 32 patients to demonstrate safety over extended periods of application to further support product application periods of 24 to 48 hours, which we believe will enhance convenience and compliance. Patients with DFUs and VLUs are randomized to either EscharEx or gel vehicle treatment at a ratio of 2:1. We expect to complete the second cohort of the Phase 2 study and to report top-line data in mid-2017," concluded Mr. Cohen.

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. 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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