



MediWound Announces Positive Top-Line Results from Its Pivotal Phase 3 Study (DETECT) in NexoBrid® for Eschar Removal of Severe Thermal Burns

January 22, 2019

Met Primary and All Secondary Endpoints with Statistically Significant Results Compared with Control Group

Conference call with MediWound management and U.S. key opinion leader begins today, January 22, 2019 at 10:00 a.m. Eastern time

YAVNE, Israel, Jan. 22, 2019 (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 that it has met its primary and all secondary endpoints in its pivotal U.S. Phase 3 clinical study (DETECT) with NexoBrid to treat patients with deep partial thickness (DPT) and full thickness (FT) thermal burns intended for submission for Biological License Application (BLA) from U.S. Food and Drug Administration (FDA).

"We are thrilled to announce these robust positive results across all endpoints, which corroborate our previous positive EU Phase 3 clinical study results and clearly demonstrate the significant beneficial impact NexoBrid has on patients' lives," said Gal Cohen, President and Chief Executive Officer of MediWound. "Our innovative product, NexoBrid, represents a new paradigm in burn care management. These significant results clearly confirm its ability to remove the eschar earlier while significantly reducing patients' surgical burden, two outcomes that are both clinically and pharmaco-economically important."

NexoBrid Phase 3 Study Design and Objectives

The NexoBrid DETECT study is a prospective, controlled, multi-center, multi-national, assessor blinded Phase 3 study in 175 patients randomized to either NexoBrid, Standard of Care (SOC), or the Gel Vehicle placebo at a ratio of 3:3:1, with 12- and 24-month long-term safety follow-up. The study involves 44 burn centers. The study objectives are to evaluate the efficacy and safety of NexoBrid by removing burn eschar earlier and reducing surgical burden and related blood loss in hospitalized patients with severe burns.

Complete eschar removal was the primary endpoint of the study and was tested against the Gel Vehicle control arm. The primary analysis was based on whether complete eschar removal was achieved in all target wounds of a patient. The analysis compared all randomized patients to the NexoBrid arm to all randomized patients to the Gel Vehicle control arm.

Secondary endpoints included reduction in the need for surgical eschar removal (surgical burden), earlier eschar removal, and blood loss, which were tested against the SOC control arm. All secondary endpoints were analyzed and compared all patients randomized to the NexoBrid arm to all patients randomized to the SOC control arm.

Time to complete wound closure (non-inferiority) and other standard safety measurements were also compared with the SOC control arm.

Funding and support for this pivotal U.S. Phase 3 clinical study (DETECT) with NexoBrid is provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. HHSO100201500035C.

Demographics and other baseline characteristics

The overall patient demographics and wound baseline characteristics were comparable across study arms.

Summary of Study Results

	NexoBrid	Gel Vehicle placebo	Standard of Care	P-value
Primary end point:				
Incidence of complete debridement	93.3% (70/75)	4.0% (1/25)	NA	P<0.0001
Secondary endpoints:				
Incidence of surgical eschar removal	4.0% (3/75)	NA	72.0% (54/75)	P<0.0001
Time to achieve complete eschar removal	1.0 days	NA	3.8 days	P<0.0001
Blood loss	14.2 ml	NA	814.5 ml	P<0.0001
Safety endpoints:				
Non inferiority in time to complete wound closure		NA		P=0.0003

Primary Endpoint

The study met its primary endpoint with statistical significance. Patients treated with NexoBrid demonstrated a significantly higher incidence of complete eschar removal compared with patients treated with the Gel Vehicle (NexoBrid: 93.3% (70/75) vs. Gel Vehicle: 4.0% (1/25), p<0.0001¹).

Secondary Endpoints

The study included secondary endpoints that were all met with statistical significance and provided further insight on several efficacy parameters.

Patients treated with NexoBrid demonstrated a significantly lower incidence of surgical eschar removal compared with patients treated with SOC

(NexoBrid: 4.0% (3/75) vs. SOC: 72.0% (54/75), $p < 0.0001^2$).

Patients treated with NexoBrid demonstrated a significantly shorter time to achieve complete eschar removal compared with patients treated with SOC (median time - NexoBrid: 1.0 days vs. SOC: 3.8 days, $p < 0.0001^3$).

Patients treated with NexoBrid incurred significantly lower blood loss during the eschar removal procedure compared with patients treated with SOC (mean volume – NexoBrid: 14.2 ml vs. SOC: 814.5 ml, $p < 0.0001^4$).

Safety

Patients treated with NexoBrid had a non-inferior time to complete wound closure compared with patients treated with SOC ($p = 0.0003^5$).

The overall safety profile of NexoBrid in the study is good, and consistent with the safety data known from previous studies.

Long-Term Safety Follow up

The planned twelve-month and twenty four-month safety follow-ups for cosmesis, function, quality of life and safety measurements are ongoing, and the Company expects to submit to the FDA the analysis of the twelve-month safety follow up in the first half of 2020 and of the twenty four months safety follow-up in the first half of 2021.

Biological License Application (BLA) Submission Plan

The Company plans to submit the BLA in the second half of 2019 based on the above available acute primary, secondary, and safety data with the twelve-month safety follow-up data submitted during the BLA review, subject to FDA concurrence at a pre BLA meeting planned for first half of 2019.

“This Phase 3 study is one of the most comprehensive randomized controlled studies ever conducted in burn care, and we are very pleased to see such compelling results,” stated Prof. Lior Rosenberg, M.D., Chief Medical Technology Officer of MediWound. “The ability to promptly and effectively remove the eschar while significantly reducing surgical burden on patients, as well as on healthcare systems, can play a major role in mass casualty events where surgical capacity is limited. We would like to take this opportunity to thank BARDA for their overall support for this project.”

Stephen T. Wills, MediWound’s Chairman added, “We thank all of the Principal Investigators, their teams, and our management and team for their tireless work and endless commitment in an effort to advance burn care. Based on these highly compelling top-line phase 3 results, it is gratifying to know that NexoBrid is one step closer to being available to help burn victims in the U.S., and we look forward to submitting a BLA in the second half of 2019, subject to FDA concurrence.”

Conference Call

MediWound management will host a conference call for investors today, January 22, 2019 beginning at 10:00 a.m. Eastern Time with a U.S. key opinion leader, Dr. Jeremy Goverman, MD, FACS, Assistant Professor of Surgery at Harvard Medical School, specializing in the treatment of Burns, Scars, and Complex Wounds, to discuss these results and answer questions. Shareholders and other interested parties may participate in the conference call by dialing 866-548-4713 (in the U.S.), 1809 212 883 (Israel), or 323-794-2093 (outside the U.S. & Israel) and entering passcode 3700005. The call also will be broadcast live on the Internet on the Company’s website at <http://ir.mediwound.com/events-and-presentations>.

A replay of the call will be accessible two hours after its completion through February 05, 2019 by dialing 844-512-2921 (in the U.S.) or 412-317-6671 (outside the U.S.) and entering passcode 3700005. The call will also be archived on the Company website for 90 days at www.mediwound.com.

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, South-Korean and Russian 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.

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.

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¹ Fisher's exact test

² Logistic regression model - Wald test

³ Generalized Wilcoxon-Gehan test

⁴ Wilcoxon test pooled using Rubin's rules

⁵ Accelerated failure time model



Source: MediWound Ltd.