MediWound Launches EscharEx® U.S. Clinical Development Program

July 22, 2019

Company's primary focus turns to EscharEx following its successful collaboration for NexoBrid

Company to initiate an adaptive comprehensive adequately controlled study in 4Q 2019

Company to host Analyst Day today, July 22, in New York, NY

YAVNE, Israel, July 22, 2019 (GLOBE NEWSWIRE) -- MediWound Ltd. (the "Company") (Nasdaq: MDWD), a fully-integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, today announced its U.S. clinical development plan for EscharEx, the Company's topical biological drug candidate for the debridement of chronic and hard-to-heal wounds. MediWound plans to initiate an adaptive comprehensive adequately controlled Phase 2 study in the fourth quarter of 2019 for second generation EscharEx. The study is designed to assess safety, efficacy and clinical benefit of EscharEx compared to placebo (gel vehicle) control and non-surgical standard of care (enzymatic and autolytic debridement) with a pre-defined interim assessment. The Company will outline development status of EscharEx and its clinical development program at its Analyst Day to be held today, July 22, 2019 in New York, NY.

"We are very excited about the EscharEx opportunity and its medical and commercial potential in the chronic wound market," said Sharon Malka, Chief Executive Officer of MediWound. "We have optimized our product candidate, and our decision to move forward with our improved second generation of EscharEx is driven by a thorough analysis of the wound healing landscape, having gathered relevant data from the market, the medical community, potential commercial partners and government agencies. This advanced generation of EscharEx has been designed in accordance with the current treatment workflow and reimbursement programs, providing a non-surgical easy-to-use, potent product for daily application, which we believe will enhance patient compliance and improve quality of care. Based on the feedback received from different stakeholders, we believe that our second generation EscharEx can better address the unmet medical need for non-surgical rapid and effective product, particularly in the outpatient setting, where the majority of patients are treated, and has a greater potential to achieve substantial market share."

Mr. Malka continued, "Importantly, based on communication with the FDA, we are very pleased to be able to leverage the data generated both from NexoBrid and from EscharEx first-generation studies. Accordingly, we have designed an adaptive comprehensive adequately controlled study comparing EscharEx to placebo control arm as well as head-to-head with the current non-surgical standard of care in the U.S. We plan to initiate the study in the fourth quarter of 2019 and anticipate conducting an interim assessment by the end of 2020."

The study is designed as a multicenter, prospective, randomized assessor-blinded study to treat venous leg ulcer (VLU) patients, in about 25 clinical sites, primarily in the U.S. The study is expected to enroll 174 patients randomized to either EscharEx, gel vehicle placebo or non-surgical standard-of-care of either Santyl or Hydrogel (SOC), at a ratio of 1:1:1, with a 3 months follow-up and with an interim assessment for futility and sample size adjustment, once the trial has achieved approximately 50% of the target patients enrollment. Incidence of complete debridement will be the primary endpoint compared to gel vehicle placebo. Secondary endpoints will include reduction of pain, time to achieve complete debridement, reduction of wound area, granulation tissue and quality of life, and will be compared with gel vehicle placebo and SOC. Incidence and time to achieve wound closure will be assessed as safety measurement.

Mr. Malka concluded, "Our collaboration announced earlier this year with Vericel to commercialize NexoBrid in the U.S. provides us with the financial resources to develop our second generation EscharEx. We are excited to pursue our clinical pathway for our second generation EscharEx and strongly believe that our approach addresses a significant unmet medical need with a sizable market opportunity. We have a clear path forward, deep clinical expertise, and a strong balance sheet to advance EscharEx into late-stage clinical development through BLA submission."

The Company's next steps, trial design, and additional market information will be highlighted at its Analyst Day to be held today, July 22, 2019 at 12:00 p.m. Eastern Time in New York City. Click here to register for the event. Members of the media and the public are invited to participate via the live webcast.

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® has demonstrated in clinical trials, with statistical significance, the ability to non-surgically and rapidly remove the eschar earlier and without harming viable tissue. The product has received marketing authorization from the European Medicines Agency as well as the Israeli, Argentinian, South Korean, Russian and Peruvian Ministries of Health. MediWound's second innovative product, EscharEx® is a topical biological drug candidate for the debridement of chronic and other hard-to-heal wounds using the same proteolytic enzyme

technology as NexoBrid. In two Phase 2 studies, EscharEx has demonstrated safety and efficacy in the debridement of various 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 design of the Phase 2 study, the timeline for the Phase 2 study and the interim report; our development plan for second generation EscharEx; expected revenues from Vericel and the ability to fund the development of EscharEx until BLA submission; the ability to fit EscharEx into treatment workflow and reimbursement programs; our expectations regarding the wound care market; and the ability to successfully develop and commercialize EscharEx. 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 important factors. In particular, you should consider that the FDA may not consider the Phase 2 study to be an adequate controlled study for the purpose of filing a BLA; the uncertain, lengthy and expensive nature of the product development process; the timing and conduct of our trials of NexoBrid, EscharEx and our other pipeline product candidates, including the timing, progress and results of current and future preclinical studies and clinical trials, and our research and development programs; risks related to our collaboration with Vericel; our ability to obtain marketing approval of NexoBrid and EscharEx in the U.S. or other markets; the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of NexoBrid, EscharEx and our pipeline products; our expectations regarding future growth, including our ability to develop new products; our commercialization, marketing and manufacturing capabilities and strategy; risks related to our contract with the U.S. Biomedical Advanced Research and Development Authority; market acceptance of our products and product candidates; the possibility of unfavorable pricing regulations or lack of coverage by third parties and reimbursement policies; our operating expenses and history of net losses; our dependence on third party suppliers; our dependence on our manufacturing facility in Yavne, Israel and manufacturing-related risks; our ability to maintain adequate protection of our intellectual property; side effects of our products and product candidates; competition risks; exchange rate fluctuations; litigation risks; risks related to our operations in Israel; our estimates regarding expenses, future revenues, capital requirements and the need for additional financing; the impact of government laws and regulations; and the additional risks discussed under the heading "Risk Factors" in our annual report on Form 20-F for the year ended December 31, 2018 as well as 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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