MediWound Initiates U.S. Phase 2 Adaptive Design Study of EscharEx® for Treatment of Venous Leg Ulcers

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Interim assessment anticipated by end of 2020

YAVNE, Israel, Dec. 03, 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 the initiation of patient treatment in its U.S. Phase 2 adaptive design clinical study of EscharEx, a topical biologic drug candidate designed to enzymatically debride chronic wounds, for the treatment of venous leg ulcers (VLU's). The trial is designed to assess safety and efficacy of EscharEx compared to gel vehicle (placebo control) and non-surgical standard-of-care (either enzymatic or autolytic debridement), and includes a pre-defined interim assessment anticipated by the end of 2020.

"We are thrilled to initiate this U.S. Phase 2 adaptive design study of EscharEx, that is built on extensive prior research, including the positive data from the completed Phase 2 study of the first-generation EscharEx," said Sharon Malka, Chief Executive Officer of MediWound. "The study enables the comparison of EscharEx to placebo control, as well as a head-to-head comparison with the current non-surgical standard of care in the U.S."

Mr. Malka continued, "We believe EscharEx is a game-changer, addressing a significant unmet medical need for patients affected by chronic wounds with a sizable market opportunity and commercial validation for enzymatic debridement. We are encouraged by the strong interest expressed in the clinical community for participating in this study, and we look forward to working closely with physicians and patients as we advance this exciting development program."

The multicenter, prospective, randomized, placebo-controlled, adaptive design study, evaluating the safety and efficacy of EscharEx in debridement of VLU's. The study is expected to enroll 174 patients at approximately 25 clinical sites, primarily in the U.S. Study participants will be randomized to either EscharEx, placebo control or non-surgical standard-of-care of either Santyl or Hydrogel, at a ratio of 1:1:1, with a three month follow-up. The study includes an interim assessment for futility and potential sample size adjustment once approximately 50 percent of patients complete treatment. The primary endpoint is incidence of complete debridement compared to gel vehicle placebo control. Secondary endpoints include time to achieve complete debridement, reduction of pain, reduction of wound area, granulation tissue and quality of life. Incidence and time to achieve wound closure will be assessed as safety measurements.

About EscharEx
EscharEx is a topically administered biological drug candidate that enzymatically debrides chronic and other hard-to-heal wounds, using the same proteolytic enzyme technology as NexoBrid. EscharEx's advanced formulation has been designed in accordance with current treatment workflow and reimbursement programs to provide a non-surgical, easy-to-use, potent therapy for once-a-day application to better address the unmet medical need for a non-surgical rapid and effective product, particularly in the outpatient setting.

In the recently completed Phase 2 study of the first-generation EscharEx formulation, EscharEx demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds. EscharEx achieved statistically significant higher incidence of complete eschar removal and demonstrated a shorter time to achieve complete debridement compared to gel vehicle.

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 studies, 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 assessment; 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 studies of NexoBrid, EscharEx and our other pipeline product candidates, including the timing, progress and results of current and future preclinical studies and clinical studies, 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.

Contacts:
Sharon Malka
Chief Executive Officer
MediWound Ltd.
ir@mediwound.com

Jeremy Feffer
Managing Director
LifeSci Advisors
212-915-2568
jeremy@lifesciadvisors.com

Source: MediWound Ltd.