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MediWound Initiates Post-Marketing Study with NexoBrid® to Treat Severe Burns in Pediatric Patients

YAVNE, Israel--(BUSINESS WIRE)-- 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 the Company has commenced a European post-marketing (Phase 3) Pediatric Investigation Plan (PIP) study to evaluate the efficacy and safety of NexoBrid® as a treatment for severe burns in children. MediWound is conducting this study as part of the European legislation concerning the development and authorization of medicines for use in children in Europe.

The prospective, randomized, controlled, multicenter study will compare NexoBrid with standard-of-care treatment in approximately 160 children between the ages of 4 and 17 with severe burns. The study is currently planned to be conducted in approximately 25 sites in Europe and Israel. Following recruitment of the 50th patient, a Data Safety Monitoring Board (DSMB) will be convened to evaluate the data and to recommend whether to allow inclusion of children between the ages of 0 and 3 to the study. The primary endpoints evaluate early eschar removal, surgical burden and cosmesis and function with a 24-month follow-up. Interim results with predefined stopping rules after a 12-month follow-up of all patients are expected to be available in the second half of 2017, with final results available in the second half of 2018.

"We are focusing on advancing our business plan and are very happy to initiate this pediatric study. The early assessment of burn severity in children, who more frequently suffer from scalding liquid burns, is very challenging, and treating children with the surgical standard-of-care is even more demanding than surgically treating adults. More than 110 children have been recruited in our past clinical studies and the clinical effects for those treated with NexoBrid in terms of earlier eschar removal, reduction in surgical burden and long-term cosmesis and function were even greater than in adults" stated Gal Cohen, President and Chief Executive Officer of MediWound.

"Advancing burn care in general and in children in particular is a highly motivating factor for us all. We strive to have NexoBrid available to benefit these young burn victims and the initiation of the PIP study is a big step toward that goal," added Mr. Cohen.

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 for removal of dead or damaged tissue, known as eschar, in adults with deep partial and full-thickness thermal burns and was 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 financial results forecast, commercial results, clinical trials and the regulatory authorizations. 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 including, but not limited to, unexpected results of clinical trials, delays or denial in the EMA regulatory approval process or additional competition in the market. 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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