MediWound Strengthens European Presence of NexoBrid®

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NexoBrid gained marketing approval in Switzerland; launch expected first quarter 2023

Launch in France expected in third quarter 2023

YAVNE, Israel, Dec. 20, 2022 (GLOBE NEWSWIRE) -- MediWound Ltd. (NASDAQ: MDWD), a fully integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced the marketing approval of NexoBrid® in Switzerland. MediWound has signed an agreement with Triskel Integrated Services to market and distribute NexoBrid in Switzerland, with a launch planned for the first quarter of 2023. Triskel also holds the distribution rights of NexoBrid in France, where NexoBrid is expected to launch in the third quarter of 2023.

“There is a high unmet need for non-surgical therapy to treat moderate-to-severe burn patients. The approval and expected launch of NexoBrid in Switzerland is another step on our journey to bring this breakthrough treatment to burn patients around the world,” said Ofer Gonen, Chief Executive Officer at MediWound. “We are pleased with the progress in Switzerland and look forward to NexoBrid’s pending reimbursement approval and launch in France, one of the most lucrative markets in Europe. We continue on our potential path towards becoming the leader in bio-therapeutic solutions for tissue repair and regeneration,” added Ofer Gonen.

Tamara Da Silva, Chief Executive Officer at Triskel, stated: "We are thrilled at this opportunity to bring NexoBrid to Switzerland and France. We believe that NexoBrid will play a major role in the future of burn care in these new markets. We are committed to bringing innovative and life changing therapies to patients in these countries and look forward to expanding our collaboration with MediWound.”

About NexoBrid

NexoBrid® (concentrate of proteolytic enzymes enriched in bromelain) is a topically administered biological product that enzymatically removes nonviable burn tissue, or eschar, in patients with deep partial and full-thickness thermal burns within four hours of application without harming viable tissue. NexoBrid is approved in 42 countries, in the European Union and other international markets, and is at registration-stage with the Food and Drug Administration (FDA) with a PDUFA target date set as of January 1, 2023. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA). NexoBrid has been designated as an orphan biologic drug in the United States, European Union and other international markets. Vericel holds an exclusive license for North American commercial rights to NexoBrid. The pivotal Phase 3 U.S. clinical study (DETECT) of NexoBrid in adult patients with deep partial-and full-thickness thermal burns up to 30% of total body surface area met its primary endpoint of complete eschar removal compared to gel vehicle as well as all secondary endpoints compared to standard of care (SOC), including shorter time to eschar removal, a lower incidence of surgical eschar removal and lower blood loss during eschar removal. Safety endpoints, including the key safety endpoint of non-inferiority in time to complete wound closure compared with patients treated with SOC, were also achieved. In addition, the twelve-month and twenty-four-month follow-up safety data of cosmesis and function were found to be comparable between the treatment and SOC arms, and no new safety signals were observed. In addition, MediWound announced positive results from Phase 3 pediatric study (CIDS), evaluating the efficacy and safety compared with standard-of-care (SOC). The study met its three primary endpoints with a high degree of statistical significance. NexoBrid demonstrated a significant reduction in time to achieve complete eschar removal and significant reduction in wound area requiring surgical excision (surgical need) while demonstrating non-inferiority to SOC in quality of scars. The European Medicines Agency (EMA) has validated for review the Type II Variation submitted by MediWound in order to expand the current approved indication for NexoBrid into the pediatric population. MediWound expects a decision from the European Commission in the first quarter of 2023.

About MediWound Ltd.

MediWound is a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, bio-therapeutic solutions for tissue repair and regeneration. Our strategy is to leverage our enzymatic technology platform, focusing on next-generation bioactive therapies for burn care, wound care, and tissue repair.

NexoBrid, our commercial orphan biological product for non-surgical eschar removal of deep-partial and full-thickness thermal burns, is a bromelain-based biological product containing a sterile mixture of proteolytic enzymes that selectively removes burn eschar within four hours without harming surrounding viable tissue. NexoBrid is currently marketed in the European Union and other international markets. It is at the registration-stage with the United States Food and Drug Administration (FDA) with a target PDUFA date set for January 1, 2023. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx, based on the same active pharmaceutical ingredient as NexoBrid, is our next-generation bioactive topical therapeutic under development for the debridement of chronic and hard-to-heal wounds. Results from Phase 2 studies show that EscharEx is significantly more effective and faster than SOC, or placebo control, in debridement of VLU and DFUs. It has demonstrated a favorable safety and tolerability profile. MediWound has initiated discussions with the FDA regarding the EscharEx pivotal Phase 3 study design.

MW005 is our topical biological drug under development for the treatment of low-risk Basal Cell Carcinoma (BCC). Its proprietary formulation is designed for safe and easy self-administration. It contains the same active pharmaceutical ingredient as NexoBrid and EscharEx. In a Phase I/II open-label, multicenter, randomized clinical trial conducted in the U.S., MW005 was shown to be safe, well-tolerated, and an effective treatment for BCC with patients demonstrating complete clinical and histological clearance of target lesions. Based on these positive results, we will continue enrolling patients, in the Phase I/II study optimizing its dosing regimen and application technique. The final results are expected in 2023.

Committed to innovation, we are dedicated to improving standard of care and enhancing patient lives. For more information, please visit www.mediwound.com.

Cautionary Note Regarding Forward-Looking Statements

MediWound cautions you that all statements other than statements of historical fact included in this press release that address activities, events, or developments that we expect, believe, or anticipate will or may occur in the future are forward-looking statements. Although we believe that we have a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting us and are subject to risks, assumptions, uncertainties, and factors, all of which are difficult to predict and many of which are beyond our control. Actual results may differ materially from those expressed or implied by the forward-looking statements in this press release. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "continues," "believe," "guidance," "outlook," "target," "future," "potential," "goals" and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "could," "may," or similar expressions .

Specifically, this press release contains forward-looking statements concerning the anticipated commercial potential, progress, development, study design, expected data timing, objectives anticipated timelines, and expectations of our products and product candidates. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the market potential and acceptance of our products and product candidates, and uncertain, lengthy and expensive nature of the product development process; the timing and conduct of our studies of our products and product candidates, including the timing, progress and results of current and future clinical studies, and our research and development programs; the approval of regulatory submission by the European Medicines Agency, FDA or by any other regulatory authority, our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets. For Example the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of our products and products; our expectations regarding future growth, including our ability to develop new products; risks related to our contracts with BARDA; our ability to maintain adequate protection of our intellectual property; competition risks; the need for additional financing; the impact of government laws and regulations and the impact of the current global macroeconomic climate on our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of our products and product candidates in the future.

These and other significant factors are discussed in greater detail in MediWound's annual report on Form 20-F for the year ended December 31, 2021, filed with the Securities and Exchange Commission ("SEC") on March 17, 2022, Quarterly Reports on Form 6-K and other filings with the SEC from time-to-time. These forward-looking statements reflect MediWound's current views as of the date hereof and MediWound undertakes, and specifically disclaims, any obligation to update any of these forward-looking statements to reflect a change in their respective views or events or circumstances that occur after the date of this release except as required by law.

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