MediWound Expands Global Presence as NexoBrid® Gains Approval in India

December 13, 2022

Exclusive marketing and distribution agreement signed with Bharat Serum and Vaccines Limited (BSV), a leading biopharmaceutical company

YAVNE, Israel, Dec. 13, 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 it has gained marketing approval of NexoBrid® in India. MediWound has signed an agreement granting Bharat Serums and Vaccines Limited (BSV), a leading biopharmaceutical company in India, the exclusive right to market and distribute NexoBrid in India for the treatment of severe burns. BSV is expected to begin commercializing NexoBrid in India in the first half of 2023.

"Today's approval of NexoBrid is a significant turning point for burn care patients and their families in India. NexoBrid offers a potentially transformative option for this population, and we are grateful that BSV has recognized the significance of the unmet medical need that NexoBrid addresses. At MediWound, we are working with health officials globally to make NexoBrid available to burn patients worldwide, beyond the 42 countries where it is already approved," said Ofer Gonen, Chief Executive Officer.

Vishwanath Swarup, COO Domestic Operations, BSV added, "Burn treatment continues to remain a public health challenge in India. According to the National Health Portal of India, as many as seven million burn injuries are reported, with mortality rates as high as 140,000 per year. With proven scientific evidence of alleviating the known risks associated with eschar, such as infection, eventual sepsis, wound deterioration, and consequential scarring, NexoBrid allows physicians to reach an informed decision on further treatment at an earlier stage, thereby ensuring safer and more effective treatment."

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.

About Bharat Serums and Vaccines Limited (BSV)

BSV has been a pioneer in the development of blood components and therapeutic antibody products for infectious and non-infectious diseases. For over four decades, BSV has focused on utilizing its scientific resources to develop several biological, biotechnology and pharmaceutical products to treat various types of diseases, contributing to preserve, protect and enhance the quality of life. We aim to be a leading biopharmaceutical company driven by people & science to set benchmarks in patient outcomes in Women's Health, Critical Care & Emergency Medicine. For further information, please visit: www.bsvgroup.com

About MediWound

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 and is at the registration-stage with the United States Food and Drug Administration (FDA) with a target PDUFA date set as of January 1, 2023. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx is our next-generation bioactive topical therapeutic under development for the debridement of chronic and hard to heal wounds. EscharEx is well-tolerated and has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a few daily applications in several Phase 2 trials. MediWound initiated discussions with the FDA regarding the EscharEx pivotal Phase 3 study design.

MW005, our topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development. The initial data from a Phase I/II study showed MW005 to be safe and well-tolerated, with a majority of the patients who completed the study with MW005 achieving complete histological clearance of their target lesions. The Company anticipates announcing the final data in the fourth quarter of calendar year 2022.

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 expectations and commercial potential, the anticipated progress, development, study design, expected data timing, and objectives anticipated timelines, of our products and product candidates. Among the factors that may cause results to be materially different from those stated herein are the market potential of our products and product candidates, the inherent uncertainties associated with the 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; market acceptance of our products and product candidates; 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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