MediWound Continues Global Expansion with Distribution Agreement for NexoBrid in United Arab Emirates with Ghassan Aboud Group

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YAVNE, Israel, Dec. 14, 2020 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, today announced it has further expanded its NexoBrid® global presence and entered the Middle Eastern markets with the signing of a distribution agreement granting Ghassan Aboud Group (GAG), an international conglomerate based in the United Arab Emirates (UAE), an exclusive right to market and distribute NexoBrid in UAE for the treatment of severe burns. Commercialization of NexoBrid in the UAE will commence upon securing regulatory approval, which is expected within a year.

"We are truly excited to partner with GAG to bring NexoBrid to the UAE," said Sharon Malka, Chief Executive Officer of MediWound. "This partnership is an important consequence of the Abraham Accords Peace Agreement signed recently between Israel and the UAE. GAG, through its healthcare arm, Gaelan Medical Trade LLC, has extensive knowledge and experience in wound care and has a strong reach into the major clinical institutions in the UAE. We are proud to enter into our first partnership in the Middle East, and believe that, together with GAG, we will be able to open up new opportunities for NexoBrid across the region, providing burn specialists with a new paradigm for the treatment of severe burns, which can improve patients' lives and the quality of their care."

Ghassan Aboud, Chairman of Ghassan Aboud Group stated, "We are pleased to partner with MediWound to bring NexoBrid to our markets in the UAE. Our goal is always to pioneer, excel and make an impact, which we have been doing so for 26 years now. I am certain that with our extensive distribution network and market reach, and with MediWound's innovative drug we will be able to improve the standard of care of burn patients and I strongly believe NexoBrid will be an instrumental part of the future treatment for burn patients everywhere."

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 the European Union and other international markets and has been designated as an orphan biologic drug in the United States, European Union, and other international markets. Vericel Corporation holds an exclusive license for North American commercial rights to NexoBrid. In January 2019, MediWound announced positive top-line results from the acute phase of 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 percent of total body surface area. The study 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. On September 16, 2020, the FDA accepted for review the Company's Biologics License Application (BLA) for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns and was assigned a Prescription Drug User Fee Act (PDUFA) target date of June 29, 2021.

About Ghassan Aboud Group

Ghassan Aboud Group is an international conglomerate that has been engaged in several key business sectors including health care, automotive, hospitality, real estate, retail, catering, logistics, pastoral, trade and distribution and media for more than two decades.

Headquartered in the United Arab Emirates, GAG's business operations are complemented by offices in Australia, Belgium, Jordan and Turkey. Ghassan Aboud Group believes that productivity, innovation and transformation require community engagement and ensures that its exclusive portfolio operates in a corporate conscious and a responsible manner making people the number one priority behind its vision "Being at the forefront of excellence".

Gaelan Medical, GAG's UAE based healthcare and beauty distribution business follows a mission of care and cure and is dedicated to support healthcare providers with world-class solutions to better serve communities across the GCC region. Gaelan medical with its experienced management team, caters to diverse healthcare needs including, pharmaceuticals, medical consumables, medical equipment and beauty products. The company's flexibility and strong financial capabilities of its parent company GAG makes it the preferred partner-of-choice and one stop solution for the region.

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, non-surgically and rapidly removes burn eschar 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 for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns. On June 29, 2020, a biological license application (BLA) was submitted to the U.S. FDA and was assigned a Prescription Drug User Fee Act (PDUFA) target date of June 29, 2021. 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

MediWound caution 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 progress, development, objectives, expectations, and commercial potential of. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with product development activities; the timing or likelihood of regulatory approvals; the ability to successfully develop and commercialize NexoBrid, including its commercial growth potential and the market demand for the product; competitive developments; whether FDA will accept all or part of the BLA and provide marketing approval for NexoBrid in the United States; the impact of applicable laws and regulations; and the uncertainties associated with the scope, scale and duration of the impact of the COVID-19 pandemic. For example, we are unable to predict how the pandemic will affect the overall healthcare infrastructure, including the pace with which governmental agencies, such as the FDA, will review and approve regulatory submissions. Additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation efforts also may impact our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of NexoBrid 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, 2019, filed with the Securities and Exchange Commission ("SEC") on February 25, 2020, 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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