



MediWound Continues NexoBrid's Global Expansion Through a New Distribution Agreement in Australia, New Zealand and Singapore with Balance Medical

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YAVNE, Israel, Jan. 02, 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 the signing of a distribution agreement granting Balance Medical Pty Ltd. the exclusive rights to market and distribute NexoBrid® in Australia, New Zealand and Singapore for the treatment of severe burns. NexoBrid is a topically-administered biologic product that removes eschar in patients with deep partial and full-thickness thermal burns, which is approved in the European Union and other international markets. Commercialization of NexoBrid in these territories will commence after receipt of the respective local regulatory authorities approval, which is expected within two years. Balance Medical will employ a special access scheme (SAS) in Australia, to allow treatment of patients prior to marketing approval, using unapproved therapeutic medicines under exceptional clinical circumstances.

"We are pleased to partner with Balance Medical as a distributor of NexoBrid to Australia, New Zealand and Singapore. We are confident that Balance Medical's local regulatory and market access expertise and proven track record of driving market penetration will maximize the medical and commercial potential of NexoBrid in these territories," stated Sharon Malka, Chief Executive Officer of MediWound. "This distribution agreement is part of our global commercialization strategy to expand global use of NexoBrid to international markets via collaborations with local partners and through additional marketing approvals. We are delighted that patients in these countries will have access to NexoBrid as Balance Medical turns NexoBrid into standard of care in Australia, New-Zealand and Singapore.

"We are thrilled at this opportunity to introduce NexoBrid to Australia, New Zealand and Singapore as it demonstrates a significant improvement to burn patients outcomes," said Shawn Garson, Managing Director of Balance Medical. "Broad evidence-based clinical studies and firsthand experience of worldwide leading experts treating burn patients in routine and mass casualty incidents demonstrate that NexoBrid may play a major role in the future of burn care in these countries. It is yet another milestone in our commitment to bring innovative and life changing therapies to patients in Australia, New Zealand and Singapore. We look forward to collaborating with MediWound towards successful register and launch of NexoBrid in Australia, New Zealand and Singapore."

About NexoBrid

NexoBrid 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 agent in the United States, European Union and other international markets.

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% 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 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. Filing of the Biological License Application to the U.S. food and Drugs Administration is expected in the second quarter of 2020.

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. 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.

About Balance Medical Pty. Ltd.

Balance Medical focuses on bringing unique and innovative medical technologies to the Australian and New Zealand markets.

Following a number of novel products in both the wound care and surgical specialties realms, NexoBrid will further differentiate Balance Medical's portfolio to deliver truly superior patient outcomes. Balance Medical's technologies are currently represented in numerous state health and private hospital agreements and contracts, reflecting the financial and clinical value of its products to the market. Balance Medical focuses on understanding the needs of its customers and launching products to meet these expectations. The Balance Medical team has extensive experience and knowledge to facilitate rapid commercialization and adoption of NexoBrid by the target markets. For more information, visit www.balancemedical.com.au

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. 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 statements that are not historical facts, and are based on Vericel's and 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, including but not limited to the ability to successfully develop and commercialize NexoBrid; the ability to submit to FDA a BLA in the timeframe expected; the ability to fund the development of NexoBrid until BLA submission; FDA may not accept part or all of the BLA; FDA may not provide marketing approval for NexoBrid in the United States; risks related to the timing and conduct of our NEXT; risks related to the contract with the U.S. Biomedical Advanced Research and Development Authority; the impact of government laws and regulations; and the additional risks discussed under the heading "Risk Factors" in MediWound's annual report on Form 20-F for the year ended December 31, 2018, Quarterly Reports on Form 6-K and other filings with the Securities and Exchange Commission ("SEC"). 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.

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