MediWound Enters into Exclusive License Agreement with Vericel for Commercial Rights to NexoBrid® in North America

May 7, 2019

$17.5 million upfront, sales royalties and up to $132.5 million in potential milestones

Leverages Vericel's Commercial Capabilities and Presence in U.S. Burn Care Market

Biologics License Application (BLA) Filing Planned for Fourth Quarter of 2019

Company to Host a Conference Call Today at 8:00 am ET

YAVNE, Israel, May 07, 2019 (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 that it has entered into exclusive license and supply agreements with Vericel Corporation (Nasdaq: VCEL) to commercialize NexoBrid® in North America (NA). 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. The pivotal U.S. phase 3 DETECT clinical study met its primary and all secondary endpoints, and the submission of the Biological License Application (BLA) to the U.S. Food and Drug Administration (FDA) is planned for the fourth quarter of 2019.

Pursuant to the agreements, MediWound will be responsible for the development activities of NexoBrid to obtain U.S. marketing approval from the FDA, supported and funded by BARDA, as well as the manufacture and supply of NexoBrid. MediWound retains the commercial rights to NexoBrid in all non-North American territories. Under the terms of the license agreement, Vericel will make an upfront payment to MediWound of $17.5 million, with an additional $7.5 million payment contingent upon U.S. BLA approval and up to $125 million in payments contingent upon meeting certain annual sales milestones. Vericel will also pay MediWound tiered royalties on net sales ranging from high single-digit to low double-digit percentages, a split of gross profits on committed BARDA procurement orders and a double-digit royalty on any additional future BARDA purchases of NexoBrid. Under the terms of the supply agreement, Vericel will procure NexoBrid from MediWound at a transfer price of cost plus a fixed margin percentage.

"We are very pleased with this collaboration with Vericel, a company with significant expertise and commercial infrastructure in place in the burn care community. This deal is strategic for both parties and we believe Vericel is the ideal commercial partner to drive market penetration to maximize the medical and commercial potential of NexoBrid in North America," stated Stephen T. Wills, MediWound's Chairman.

Mr. Wills continued, "As our comprehensive strategic process evolved, we concluded that licensing NexoBrid was the right first step towards monetizing our development programs and create near-term value. The cash flow from this transaction provides us with the funds to significantly advance EscharEx, our topical biologic drug candidate for the debridement of chronic and other hard-to-heal wounds, through BLA filing. Based on the multiple indications of interest EscharEx received during the strategic process, we believe that EscharEx has the potential to have a meaningful impact on wound care treatment and become a dominant debriding agent in the marketplace. While we will always assess potential strategic opportunities, this licensing deal gives us flexibility regarding the timing to monetize EscharEx and maximize shareholder value."

Sharon Malka, MediWound's Chief Executive Officer, commented, "The collaboration with Vericel, an active player with commercial presence in the U.S. burn care market, further validates the clinical and commercial value of NexoBrid as a new paradigm in burn care management. We have an upcoming pre-BLA meeting scheduled with the FDA, and subject to FDA concurrence, plan to file the BLA later this year. Regarding NexoBrid in non-North American territories, we will be directing our attention towards greater market penetration by adding new distributors and obtaining additional marketing approvals. Importantly, we believe that the proceeds generated from this collaboration, combined with existing cash on hand, will allow us to advance and optimize the ongoing development of EscharEx through BLA filing. We expect to commence the next step of the EscharEx clinical development program in the second quarter of 2019."

"We are very pleased with this agreement to commercialize NexoBrid in North America," stated Nick Colangelo, President and Chief Executive Officer of Vericel. "We are excited to collaborate with the MediWound team to obtain FDA approval for NexoBrid and integrate this innovative and critical product into our burn product portfolio. We believe that NexoBrid is an excellent strategic fit that can help increase penetration of Epicel and enable us to treat additional patients and capture a larger share of the North American burn care market."

MediWound announced in January 2019 that it met its primary and all secondary endpoints in its pivotal U.S. Phase 3 DETECT clinical study with NexoBrid to treat patients with deep partial thickness and full thickness thermal burns. DETECT was a prospective, controlled, multi-center, multi-national assessor-blinded Phase 3 study in 175 patients at 44 burn centers randomized to either NexoBrid, Standard of Care, or the Gel Vehicle placebo at a ratio of 3:3:1, with 12- and 24-month long-term safety follow-up. The study met its primary endpoint of complete eschar removal, as well as secondary endpoints of reduction in the need for surgical eschar removal (surgical burden), earlier eschar removal, and blood loss.

The BLA currently is targeted for submission to the FDA in the fourth quarter of 2019 based on the acute primary, secondary and safety data, with the analysis of the twelve-month safety follow-up data submitted during the BLA review and the twenty-four-month safety follow-up data submitted as BLA supplements, subject to FDA concurrence at a pre-BLA meeting planned for the second quarter of 2019.

Funding and support for NexoBrid development costs required to obtain marketing approval in the U.S., including the ongoing DETECT study and a Phase 3 pediatric (CIDS) study is provided by BARDA, under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. HHSO100201500035C and HHSO100201800023C. The contracts also include a $16.5 million commitment for procurement of NexoBrid contingent upon FDA eligibility for use in an emergency or FDA marketing approval. The contract provides an option to fund up to $50 million for additional NexoBrid procurement

Moelis & Company acted as financial advisor to MediWound.

Conference Call
MediWound management will host a conference call for investors today, May 7, 2019 beginning at 8:00 am Eastern Time. Shareholders and other interested parties may participate in the conference call by dialing 877-602-7189 (in the U.S.), or 678-894-3057 (outside the U.S.) and entering passcode 2358328. The call will also be broadcast live on the Company's website an investor deck will be available in the Company's IR website at http://ir.mediwound.com/events-and-presentations.

A replay of the call will be accessible two hours after its completion through May 21, 2019 by dialing 855-859-2056 (in the U.S.) or 404-537-3406 (outside the U.S.) and entering the passcode 2358328. The call will also be archived on the Company website for 90 days at www.mediwound.com.

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 ® demonstrated in clinical trials, with statistical significance the ability to non-surgically and rapidly remove the eschar earlier and, without harming viable tissue. The product has received marketing authorization from the European Medicines Agency as well as the Israeli, Argentinian, South Korean and Russian Ministries of Health. MediWound's second innovative product, EscharEx® is a topical biological drug 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 chronic and other hard-to-heal wounds, within a few daily applications. For more information, please visit www.mediwound.com.

About Vericel Corporation
Vericel is a leader in advanced cell therapies for the sports medicine and severe burn care markets. The company markets two cell therapy products in the United States. MACI® (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults. Epicel® (cultured epidermal autografts) is a permanent skin replacement for the treatment of patients with deep dermal or full thickness burns greater than or equal to 30% of total body surface area. For more information, please visit the company's website at www.vcel.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 timing of regulatory filings and submissions; Vericel's ability to commercialize NexoBrid; expected payments under the license and supply agreements; anticipated uses of such payments; benefits to shareholders as a result of the collaboration with Vericel; the regulatory authorizations and launch dates. 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 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. In particular, you should consider that we may not submit the BLA to FDA in the timeframe expected, or at all; FDA may not provide marketing approval for NexoBrid in the United States and, if such approval is obtained, Vericel may not be able to successfully commercialize NexoBrid in the United States; and the risks discussed under the heading "Risk Factors" in our annual report on Form 20-F for the year ended December 31, 2018 as well as information contained in other documents filed with or furnished to the Securities and Exchange Commission. 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.

Contacts:
Sharon Malka
Chief Executive Officer
MediWound Ltd.
ir@mediwound.com

Jeremy Feffer
Managing Director
LifeSci Advisors
212-915-2568
jeremy@lifesciadvisors.com

Source: MediWound Ltd.