MediWound Expands its Distribution Agreement with GENFA MEDICA SA to Market NexoBrid in Ukraine and the Baltic States

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YAVNE, Israel, Jan. 13, 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 expansion of its agreement with GENFA MEDICA SA, granting it the exclusive right to market and distribute NexoBrid® in Ukraine, Lithuania, Latvia and Estonia adding to its current rights to distribute NexoBrid in Russia.

NexoBrid, currently approved in the European Union and other international markets, is a topically-administered biologic product that removes eschar in patients with deep partial and full-thickness thermal burns and is already approved for marketing in Lithuania, Latvia and Estonia. Commercialization of NexoBrid in Ukraine will commence after receipt of local marketing authorization, which is expected within 2 years.

"We are pleased to expand our collaboration with GENFA MEDICA SA to distribute NexoBrid in Ukraine and in the Baltic states of Lithuania, Latvia, Estonia. GENFA MEDICA SA has already launched NexoBrid in Russia, and we are confident that their knowledge of and experience with NexoBrid will enable them to maximize the commercial potential of NexoBrid in these new countries," said Sharon Malka, Chief Executive Officer of MediWound. "The expansion of our distribution agreement with GENFA MEDICA SA is a testament to our continuous effort to monetize NexoBrid by expanding to new territories. We are delighted that NexoBrid will soon be available to treat patients who are suffering from severe burns in these countries."

Yael Duberstein, Director of GENFA MEDICA SA stated, "We are thrilled at this opportunity to bring NexoBrid to Ukraine, Lithuania, Latvia and Estonia. We have successfully registered and launched NexoBrid in Russia and are confident it will play a major role in the future of burn care in these new markets as well. We are committed to bringing innovative and life changing therapies to patients in these countries and look forward to significantly expanding our collaboration with MediWound."

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 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. Filling of the Biological License Application (BLA) 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 GENFA MEDICA SA
Genfa Medica SA is a Swiss company representing a number of manufacturers of generic pharmaceutical products from Israel, Canada and other countries in the Russian pharmaceutical market. Its broad portfolio of high-quality prescription products is used mostly in reimbursed and hospital segments. According to IMS, two brands sold by Genfa Medica S.A. have been nominated leaders with the highest sales in the Russian reimbursement market: these are Genfaxon® (Interferon beta 1a) and Genfatinib® (Imatinib).

For more information, please visit www.genfamedica.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 possibility of obtaining marketing approvals in Ukraine, the ability to successfully commercialize NexoBrid in these countries and the time of filing the BLA. 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 important factors. In particular, you should consider Genfa Medica's ability to obtain marketing approval of NexoBrid in the Ukraine market; the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of NexoBrid; the expectations regarding future growth; 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; the possibility of unfavorable pricing regulations or lack of coverage by third parties and reimbursement policies; and the additional risks discussed under the heading "Risk Factors" in our 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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