

# NexoBrid® Receives Marketing Authorization from Russia's Ministry of Health

September 5, 2018

### Commercial launch is expected in the first half of 2019

YAVNE, Israel, Sept. 05, 2018 (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 receipt of authorization from the Ministry of Health in Russia to market and distribute NexoBrid<sup>®</sup> for the removal of dead or damaged tissue, known as eschar, in adults with deep partial and full-thickness thermal burns. Genfa Medica S.A., MediWound's exclusive distribution partner in Russia, received the marketing authorization and intends to launch NexoBrid in Russia in the first half of 2019.

This regulatory approval builds upon NexoBrid's marketing authorization from the European Medicines Agency (EMA) for the same indication and again validates MediWound's strategy of using the EMA approved registration file for seeking approval in different international markets around the globe.

"We are delighted that NexoBrid will soon be available to treat patients who are suffering from severe burns in Russia, our first market in Commonwealth of Independent States (CIS). The Genfa Medica team is well-regarded within the medical community they serve, and we believe their innovative marketing experience will support the adoption of NexoBrid in Russia and provide access for Russian patients to the important clinical benefits of NexoBrid," stated Gal Cohen, President and Chief Executive Officer of MediWound.

"We are pleased to continue executing on our strategy of expanding the use of NexoBrid in international markets. This approval in Russia joins the marketing authorizations from the European Medicines Agency (EMA), the Israeli, Argentinian, and South Korean Ministries of Health and supports our commercial strategy to expand the use of NexoBrid through collaboration with local companies that possess the expertise in the local regulatory, market access and marketing efforts, and assume the financial commitment and diligence. We will continue to expand our distribution channels to other markets through our on-going business development efforts, and look forward to securing additional marketing approvals," concluded Mr. Cohen"

## 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<sup>®</sup>, received marketing authorization from the European Medicines Agency as well as the Israeli, Argentinian and South Korean Ministries of Health, for removal of dead or damaged tissue, known as eschar, in adults with deep partial and full-thickness thermal burns. NexoBrid<sup>®</sup> represents a new paradigm in burn care management, and clinical trials have demonstrated, with statistical significance, its ability to non-surgically and rapidly remove the eschar earlier and, without harming viable tissues.

MediWound's second innovative product, EscharEx<sup>®</sup> is a topical biological drug being developed for debridement of chronic and other hard-to-heal wounds and is complementary to the large number of existing wound healing products, which require a clean wound bed in order to heal the wound. EscharEx<sup>®</sup> contains the same proteolytic enzyme technology as NexoBrid<sup>®</sup>, and benefits from the wealth of existing development data on NexoBrid<sup>®</sup>. In two Phase 2 studies, EscharEx<sup>®</sup> 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 Genfa Medica, S.A.

Genfa Medica S.A. is a Swiss company representing pharmaceutical manufacturers from Argentina, Israel and Canada to the Russian pharmaceutical market. Its broad portfolio of high-quality prescription products is used mostly in reimbursed and hospital segments. According to IMS, three brands sold by Genfa Medica S.A. have been nominated leaders with the highest sales in the Russian reimbursement market: Genfaxon, Genfatinib and Tutabin. The Association of International Pharmaceutical Manufacturers (AIPM) ranked Genfa Medica S.A. as one of the Top 10 pharmaceutical companies in the Russian reimbursement market in 2013 by market share.

## **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 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 the risks discussed under the heading "Risk Factors" in our annual report on Form 20-F for the year ended December 31, 2017 and 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 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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