

# NexoBrid® Receives Marketing Authorization From South Korea's Ministry of Health

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Exclusive distributor BL&H Co., Ltd. plans commercial launch in second half of 2018

YAVNE, Israel, June 04, 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 South Korea 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. BL&H Co., Ltd., MediWound's exclusive distribution partner in South Korea, received the marketing authorization and intends to launch NexoBrid in South Korea in the second half of 2018

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

"We are delighted that NexoBrid will soon be available to treat patients in South Korea with severe burns. Founded in 1999, our partner, BL&H, supplies a number of drugs through partnership with well-known pharmaceutical companies around the world, including the U.S., Europe and Japan, and especially orphan drugs for rare disease patients in South Korea. MediWound's NexoBrid is recognized as an orphan drug in the U.S., EU and in South Korea. We are very pleased to be able to advance burn care in South Korea with NexoBrid, an effective and minimally invasive treatment modality," stated Gal Cohen, President and Chief Executive Officer of MediWound.

"This approval is in line with our commercial strategy to expand the use of NexoBrid in international markets, such as Latin America, Asia Pacific and CIS, 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 look forward to additional marketing approvals in these regions in the coming quarters as we seek to further expand our distribution channels to other markets through our on-going business development effort."

### **About NexoBrid**

NexoBrid is an easy-to-use, topical pharmaceutical product that removes dead or damaged tissue, known as eschar, in four hours without harming the surrounding healthy tissues. NexoBrid was granted marketing authorization from the European Medicines Agency and Israeli Ministry of Health for the removal of eschar in adults with deep partial and full-thickness thermal burns, and was commercially launched in Europe and in Israel. Representing a new paradigm in burn care management, NexoBrid demonstrated in clinical studies, with statistical significance, its ability to non-surgically and rapidly remove the eschar earlier than other modalities, without harming viable tissues. The removal of eschar or "debridement" is a critical first step in the successful healing of severe burns and chronic and other hard-to-heal wounds. With the current standard of care, burn eschar is removed either with existing topical agents that have been found to be minimally effective or that take a significantly longer period of time to work, or by resorting to non-selective surgery, which is traumatic and may result in loss of blood and viable tissue.

### 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 BL&H Co., Ltd.

BL&H meets the demands of healthcare professionals by providing access to advanced and innovative products that offer patients a better quality of life. BL&H combined business, medical, regulatory and scientific expertise facilitates its approach to maximizing distribution of these high-quality, cutting-edge pharmaceutical products.

For more information, please visit www.blnh.co.kr.

## **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 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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