FDA Clears Development Pathway for NexoBrid® for Sulfur Mustard Injuries

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YAVNE, Israel, May 29, 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 that following a meeting with the U.S. Food and Drug Administration (FDA), the Agency agreed that MediWound's development plan for NexoBrid for the debridement of skin injuries inflicted by Sulfur Mustard (a chemical warfare agent, typically dispersed as a fine mist of liquid droplets) in adults and children, would be in accordance with the Animal Rule, as it is neither ethical nor feasible to conduct human trials with chemical warfare agents. Under the Animal Rule, the FDA may grant marketing approval based on adequate and well-controlled animal efficacy studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans.

The FDA also agreed that single animal species trials would suffice, subject to adequate safety and efficiency data from the planned studies. In addition, the FDA agreed to rely on the existing Chemistry, Manufacturing and Control (CMC) information already available for NexoBrid by way of cross-reference to the existing NexoBrid IND for burns.

"We are excited about this project, as it leverages our existing enzymatic technology platform to additional indications and takes advantage of the advanced stage of development of NexoBrid, a highly effective burn care product. Ten decades of research has not produced an effective treatment for Sulfur Mustard skin injury, except for radical surgical removal of the contaminated skin. An effective non-surgical debridement agent could play a major role in a mass casualty incident involving victims exposed to Sulfur Mustard and suffering from a serious and life threating condition," stated Gal Cohen, President and Chief Executive Officer of MediWound. "Based on promising data from animal studies presented at the 2017 European Burn Association conference, indicating the potential benefit of using NexoBrid for the treatment of such Sulfur Mustard injuries, and following the meeting with the FDA, we will seek to collaborate on this program with relevant governmental entities."

About The Animal Efficacy Rule

The FDA Animal Efficacy Rule (also known as the Animal Rule) applies to development and testing of drugs and biologicals to reduce or prevent serious/life-threatening conditions caused by exposure to lethal or permanently disabling toxic agents (chemical, biological, radiological, or nuclear substances), where human efficacy trials are not feasible or ethical. The Animal Rule states that for drugs developed to ameliorate or prevent serious or life-threatening conditions caused by exposure to lethal or permanently disabling toxic substances, when human efficacy studies are not ethical and field trials are not feasible, FDA may grant marketing approval based on adequate and well-controlled animal efficacy studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans. The Animal Efficacy Rule was finalized by the FDA and authorized by the United States Congress in 2002, following the September 11 attacks and concerns regarding bioterrorism. For further elaboration see - FDA Product Development Under the Animal Rule Guidance for Industry at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm399200.htm*

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 ®, received marketing authorization from the European Medicines Agency as well as the Israeli and Argentinian Ministries of Health, for removal of dead or damaged tissue, known as eschar, in adults with deep partial and full-thickness thermal burns. NexoBrid® 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® 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® contains the same proteolytic enzyme technology as NexoBrid®, and benefits from the wealth of existing development data on 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.

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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