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MediWound Initiates Second Phase 2 Clinical Trial of EscharEx(TM) to Treat Chronic and Other Hard-to-Heal Wounds

Trial to Build Upon Earlier Study With Encouraging Outcomes in Poorly Served Multibillion-Dollar Market

YAVNE, Israel, May 21, 2014 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq:MDWD), a fully-integrated, biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, announces initiation of its second Phase 2 clinical trial of EscharEx™ to treat chronic and other hard-to-heal wounds. EscharEx™ is based on MediWound's patented proteolytic enzyme technology.

This prospective, randomized, controlled, multicenter Phase 2 study of approximately 72 subjects is planned to be conducted at approximately 10 clinical sites and intends to evaluate safety and efficacy of EscharEx compared with gel vehicle for the treatment of a variety of chronic and other hard-to-heal wounds, including diabetic foot ulcers (DFUs), venous ulcers and post-surgical or traumatic hard-to-heal wounds. The blinded study intends to assess non-viable tissue removal (debridment), wound bed preparation and wound healing as well as other additional endpoints.

The Company has concluded a Phase 2 feasibility study of EscharEx to treat chronic and other hard-to-heal wounds in 24 patients at two clinical sites in Israel. The results from that trial demonstrated efficacy in debriding various wound etiologies such as DFUs, venous ulcers, pressure sores and other post-surgical or post-trauma hard-to-heal wounds.

"Our enthusiasm for EscharEx to treat chronic and hard-to-heal wounds is based on the wealth of existing development data with our lead product, NexoBrid®, to remove eschar in severe burns as well as clinical data from our Phase 2 feasibility study with our technology in chronic and hard-to-heal wounds. As EscharEx is based on the same technology as NexoBrid®, we believe its development program is significantly de-risked and we look forward to a positive outcome with our second Phase 2 trial," stated Gal Cohen, President and Chief Executive Officer of MediWound.

"Pending clinical and regulatory success, we believe that there is significant market opportunity for EscharEx as more than 14 million people in Europe and the U.S. alone, suffer from chronic wounds. Chronic and other hard-to-heal wounds represent a $25 billion burden to the U.S. healthcare system each year. Unfortunately, the incidence of patients suffering from such chronic wound conditions is growing due to the overall aging of the population and a higher prevalence of obesity and diabetes, among other factors. There is a great unmet medical need to effectively debride such wounds in a non-surgical manner, as debriding the wound is a critical first step for healing and can provide better conditions to aid such patients. We are pleased to initiate this important study within our projected timetable, and expect to have vital data from this study in the second half of 2015," concluded Mr. Cohen.

About Chronic and Other Hard-to-Heal Wounds and Eschar

Chronic and other hard-to-heal wounds are caused by impairment in the biochemical and cellular healing processes due to local or systemic conditions, and generally can take several weeks or longer to heal.

In each of the various wound types, the presence of the eschar is a frequent cause of wound chronification and the removal of eschar is a key step to commence healing. If not effectively treated, these wounds can lead to severe complications including further infection, osteomyelitis, fasciitis, amputation and increased mortality. MediWound believes that most advanced wound care therapies, including negative pressure wound therapy and skin substitutes, would be complementary to EscharEx, as these therapies require a clean wound bed to effectively heal a wound.

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 for removal of dead or damaged tissue, known as eschar, in adults with deep partial and full-thickness thermal burns and was launched in Europe. 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. 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 U.S. 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 financial results forecast, commercial results, clinical trials and the regulatory authorizations. 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 including, but not limited to, unexpected results of clinical trials, delays or denial in the FDA or the EMA regulatory approval process or additional competition in the market. 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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