MediWound Strengthens its NexoBrid European Presence with Additional Distribution Agreements

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YAVNE, Israel, May 04, 2020 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company bringing innovative therapies to address unmet medical needs in severe burn and wound management, today announced the expansion of its NexoBrid® European presence with distribution agreements granting GENFA MEDICA SA, its distributer in Russia, Ukraine and the Baltic countries, the exclusive right to market and distribute NexoBrid in France and Switzerland and Specialty Therapeutics PC the exclusive right to market and distribute NexoBrid in Greece, Bulgaria, Malta and Cyprus.

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. Commercialization of NexoBrid in these additional regions will commence upon securing authorities approval for market access, which is expected within the next 12 months.

"We are very pleased to strengthen NexoBrid's European presence by signing new distribution agreements for additional six countries in Europe," said Sharon Malka, Chief Executive Officer of MediWound. "The addition of these distribution agreements, which cover lucrative European markets, is an extension of our commercial strategy in Europe, driven by our direct sales force accompanied with local distribution agreements, to maximize NexoBrid market potential as we continue to expand the commercialization of NexoBrid towards a substantive cash generating product. 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 the considerable market of France and to Switzerland . We are confident that Nexobrid will play a major role in the future of burn care in these new markets. We are committed to bringing innovative and life changing therapies to patients in these countries and look forward to expanding our collaboration with MediWound."

George Pavlakis, CEO of Specialty Therapeutics PC stated, "For us, as an innovative therapeutic company, NexoBrid brings a new paradigm for burn care patients, both in improving quality of care and cost of care. We are excited about this collaboration and look forward to launching NexoBrid in Greece, Cyprus, Malta and Bulgaria."

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 by mid-year 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 engaged in R&D, regulatory, support and marketing of specialty products, via its strategic partnerships with research based organizations and leading distributors in the selected markets.

For more information, please visit www.genfamedica.com

About Specialty Therapeutics PC
Specialty Therapeutics is a Greek pharmaceutical company, committed to bring innovative products in Greece, Cyprus, Malta, Bulgaria, Romania, Serbia, offering highly specialized products to address the unmet medical needs of patients in Oncology/Haematology/Radiotherapy, Endocrinology/Gynaecology, Nuclear Medicine, Immunology, Rare diseases, Wound and Burn Care area.

Specialty Therapeutics is the partner of choice for 13 multinational and specialty pharma Companies representing 23 innovative products, covering 6 countries with a population of 50 million.

For more information, please visit www.specialtytherapeutics.gr/index.html

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 France and Switzerland, the ability to successfully commercialize NexoBrid in these countries as well as in Greece, Bulgaria, Malta and Cyprus 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 or Specialty Therapeutics' ability to obtain marketing approval of NexoBrid in the relevant markets; 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, 2019, 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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