Medicus Pharma Submits Optimized Phase 2 Study Protocol to U.S. FDA for Teverelix in Acute Urinary Retention

Mechanism-Driven Study Design Focused on Capital Efficiency and Accelerated Development for Near-Term Value Creation, Addressing a $2 Billion Potential Target Market

PHILADELPHIA, April 06, 2026 (GLOBE NEWSWIRE) — Medicus Pharma Ltd. (NASDAQ: MDCX) ("Medicus" or the "Company"), a biotech/life sciences company focused on advancing the clinical development programs of novel and potentially disruptive therapeutics assets, today announced the Company has submitted an optimized Phase 2 clinical study design to the U.S. Food and Drug Administration ("FDA") for Teverelix, its investigational GnRH antagonist, for the prevention of recurrent acute urinary retention ("AURr") in men with benign prostatic hyperplasia ("BPH") as part of its existing open Investigational New Drug ("IND") for Teverelix.

The Phase 2 study design has been refined under the leadership of **Steven A. Kaplan, MD, FACS**, a globally recognized leader in urology and men's health, who will serve as Principal Investigator.

Dr. Kaplan is Professor of Urology at the Icahn School of Medicine at Mount Sinai and has held senior academic appointments at Columbia University and Weill Cornell Medical College, where he served as Vice Chairman of Urology. He is internationally regarded as a leading authority in BPH, lower urinary tract symptoms ("LUTS") and voiding dysfunction. He has also authored over 1,000 scientific publications, including more than 600 peer-reviewed articles, and is the recipient of the John K. Lattimer Award for Lifetime Achievement in Urology.

*"This refined study design reflects a more capital-efficient development strategy intended to accelerate Teverelix's path to commercialization**,"** said **Dr. Raza Bokhari, Executive Chairman and CEO of Medicu**s. "By focusing on clear pharmacodynamic endpoints and incorporating an interim analysis designed to inform subsequent clinical development, we believe Teverelix can generate actionable clinical data more rapidly, enabling earlier strategic engagement and potential partnering opportunities."*

There are currently no approved pharmacologic therapies specifically indicated to prevent recurrence of AUR, primarily due to enlarged prostate. The Company's proof-of-concept study design to evaluate Teverelix in AURr represents a novel approach addressing an underserved clinical need, representing an approximately $2 billion target market.

The updated Phase 2 study design (ANT-2111-02) incorporates:

- A targeted sample size of approximately 126 patients across the United States and Europe

- A design focused on detecting a clear pharmacodynamic signal (total prostate volume reduction)
- A structure optimized for dose and route differentiation

This design demonstrates a data-driven evolution toward generating decision-grade clinical evidence representing an approximately three-fold reduction in study size compared to the original design and a meaningful reduction in overall development cost, with corresponding improvements in development efficiency and execution speed, supporting earlier strategic engagement and partnering discussions. The study is designed to generate an early pharmacodynamic signal within approximately 12 weeks.

AURr Study Design and Endpoints Overview

The optimized Phase 2 study is a randomized, double-blind, single-dose, four-arm design. Patients will be randomized to receive:

- Teverelix 90 mg (intramuscular)
- Teverelix 120 mg (subcutaneous)
- Matched placebo controls

All patients will receive a single injection on Day 1. The duration of the study is 52 weeks, which includes a 28-week treatment period and a 24-week follow-up. The patients will remain on standard-of-care alpha-blocker therapy.

The study is anchored by a mechanism-driven primary endpoint of percent change in total prostate volume ("TPV") at Week 12. The secondary endpoints include maximum urine flow rate ("Qmax"), post void residual volume ("PVR"), AURr and need for intervention.

An interim analysis will be conducted after approximately 50 percent of patients have completed the Week 12 assessment to inform dose selection, route optimization and future Phase 3 study design. This interim analysis is expected to provide an early pharmacodynamic signal and support timely development decision.

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About Medicus Pharma Ltd.

Medicus Pharma Ltd. (Nasdaq: MDCX) is a precision-guided biotech/life sciences company focused on accelerating the clinical development programs of novel and potentially disruptive therapeutics assets. The Company is actively engaged in multiple countries across three continents.

Company's key therapeutics assets are:

***SkinJect™, a novel localized immuno-oncology precision product** focused on non-melanoma skin diseases, especially basal cell carcinoma (BCC) and **Gorlin Syndrome**, a rare autosomal dominant disease also called nevoid BCC syndrome, collectively representing a ~$2 billion market opportunity.*

***Teverelix®, a next generation GnRH antagonist** is a first-in-market product for cardiovascular high-risk advanced prostate cancer patients and patients with acute urinary retention relapse (AURr) episodes due to enlarged prostate, collectively representing a ~$6 billion market opportunity.*

The Company is actively engaged in following collaborations:

Skinject™ Platform Expansion

In August 2025, the Company announced its entry into a non-binding memorandum of understanding (MoU) with Helix Nanotechnologies, Inc. (HelixNano), a Boston-based biotech company focused on developing a proprietary advanced mRNA platform, in respect of their shared mutual interest in the development or commercial arrangement contemplated by the MoU. The MoU is non-binding and shall not be construed to obligate either party to proceed with a joint venture or any further development or commercial arrangement, unless and until definitive agreements are executed, and there can be no assurance that such definitive agreements will be executed.

The Company is exploring co-development of thermostable infectious disease vaccines combining HelixNano's proprietary mRNA technology with the Medicus microneedle array delivery platform.

Patient Access and Advocacy

In October 2025, the Company announced a strategic collaboration with the Gorlin Syndrome Alliance (GSA) to advance compassionate access to SkinJect for patients suffering from Gorlin Syndrome, also known as nevoid basal cell carcinoma syndrome.

In collaboration with the Gorlin Syndrome Alliance, Medicus is pursuing an Expanded Access IND program to provide Gorlin Syndrome patients with multiple or inoperable BCCs access to SkinJect™, the Company's investigational D-MNAs, under physician supervision.

AI Enabled Clinical Development

In December 2025, the Company signed a non-binding letter of intent to collaborate with Reliant AI Inc., a decision-intelligence company specializing in generative AI for the life sciences, to develop an AI-driven clinical data analytics platform to support capital-efficient and time-efficient clinical development through data-driven dynamic clinical-site selection, pharmacodynamic (PD) informed patient stratification, and enrollment forecasting. The initial phase of the collaboration is expected to support the upcoming Teverelix clinical study planned for 2026. There can be no assurance that a definitive agreement will be executed or that the proposed collaboration will proceed as contemplated.

Cautionary Notice on Forward-Looking Statements

Certain information in this news release constitutes "forward-looking information" under applicable securities laws. "Forward-looking information" is defined as disclosure regarding possible events, conditions or financial performance that is based on assumptions about future economic conditions and courses of action and includes, without limitation, statements regarding the Company's ability to continue as a going concern, statements regarding the Company's leadership and prospects, the collaboration with GSA including the potential benefits thereof for GSA, those suffering with Gorlin Syndrome and Medicus (including as it relates to the development of SkinJect™), ability to be approved for the Expanded Access IND Program to enable those suffering with Gorlin Syndrome to access SkinJect™ under physician-supervised treatment protocols, the development of Teverelix and expectations concerning, and future outcomes relating to, the development, advancement and commercialization of Teverelix for AURr, high CV risk prostate cancer, women's health indications like endometriosis, and the potential market opportunities related thereto, the MOU, including the potential signing of definitive agreements between Medicus and HelixNano and the development of thermostable infectious diseases vaccines by combining HelixNano's proprietary mRNA vaccine platform with Medicus's proprietary microneedle array (MNA) delivery platform, the Company's aim to fast-track the clinical development program and convert the SKNJCT-003 exploratory clinical trial into a pivotal clinical trial, and approval from the FDA and the timing thereof, including with respect to the Company's submission for approval in the FDA Commissioner's National Priority Voucher program, plans and expectations concerning, and future outcomes relating to, the development, advancement and commercialization of SkinJect through SKNJCT-003 and SKNJCT-004, and the potential market opportunities related thereto, the Company's expectations regarding reported efficacy findings, the overall response rate and potential changes thereto, and whether there will be material changes to its reported SKNJCT-003 topline results and to secure an EOP2 meeting with the FDA in the first half of 2026, entry into definitive documents with Reliant and the expected terms thereof, engaging in proposed Medicus-sponsored studies currently contemplated in the Reliant non-binding letter of intent and the expected benefits thereof, the expansion

of SKNJCT-003 into the United Kingdom and the potential benefits therefrom, the advancement of the SKNJCT-004 study and the potential results of and benefits of such study. Forward-looking statements are often but not always, identified by the use of such terms as "may", "on track", "aim", "might", "will", "will likely result", "could," "designed," "would", "should", "estimate", "plan", "project", "forecast", "intend", "expect", "anticipate", "believe", "seek", "continue", "target", "potential" or the negative and/or inverse of such terms or other similar expressions. These statements involve known and unknown risks, uncertainties and other factors, which may cause actual results, performance or achievements to differ materially from those expressed or implied by such statements, including those risk factors described in the Company's annual report on form 10-K for the year ended December 31, 2025, and in the Company's other public filings on EDGAR and SEDAR+, which may impact, among other things, the trading price and liquidity of the Company's common shares. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement and reflect our expectations as of the date hereof and thus are subject to change thereafter. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. Readers are further cautioned not to place undue reliance on forward-looking statements as there can be no assurance that the plans, intentions or expectations upon which they are placed will occur. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated.

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