Medicus Pharma Receives FDA "Study May Proceed" Clearance For Teverelix® Phase 2b Study in Advanced Prostate Cancer Patients with High Cardiovascular Risk

The Company is developing Teverelix® as a best-in-class market product for advanced prostate cancer patients with high CV risk and a first in class product for Acute Urinary Retention Relapse prevention (AURr) collectively representing ~US$6 billion in potential market opportunity

PHILADELPHIA, Feb. 10, 2026 (GLOBE NEWSWIRE) — Medicus Pharma Ltd. (NASDAQ: MDCX) ("Medicus" or the "Company"), a precision guided biotech/life sciences company focused on advancing the clinical development programs of novel and potentially disruptive therapeutics assets, is pleased to announce that it has received "study may proceed" clearance from the U.S. Food and Drug Administration (FDA) to initiate its Phase 2b dose-optimization study of Teverelix®, an investigational next generation long-acting GnRH antagonist, in men with advanced prostate cancer (APC).

Teverelix® Clinical Trial Design in Advanced Prostate Cancer

The Phase 2b study is an open-label trial enrolling 40 men with advanced prostate cancer appropriate for androgen deprivation therapy (ADT).

Participants will receive:

- A loading regimen of 180 mg intramuscular (IM) plus two 180 mg subcutaneous (SC) injections (total 540 mg), followed by
- Two 180 mg SC injections (360 mg total) on Day 29 and every six weeks thereafter

Total treatment duration is approximately 22 weeks.

The primary endpoint is confirmation of medical castration by Day 29 with sustained suppression through Day 155, with a target probability exceeding 90%.

"Teverelix Phase 2 dose optimization study in advanced prostate cancer represents an important transition point for the Teverelix program," stated Dr. Raza Bokhari, Medicus Exec. Chairman & CEO, "Our development strategy is intentionally focused on a population that remains underserved by existing therapies. If successful, we believe Teverelix has the potential to become a best-in-class GnRH antagonist and the first hormone therapy specifically supported by a Cardiovascular-risk-focused label in this setting."

Teverelix®: Differentiated Mechanism with Cardiovascular Relevance

Teverelix trifluoroacetate is a long-acting injectable GnRH antagonist formulated as a microcrystalline suspension. Unlike GnRH agonists, which induce an initial

testosterone surge, Teverelix provides immediate receptor antagonism, enabling rapid suppression of luteinizing hormone (LH), follicle-stimulating hormone (FSH), and downstream sex hormones without flare.

This mechanism may be clinically relevant in patients with advanced prostate cancer and elevated cardiovascular risk, where emerging evidence suggests persistent FSH exposure with GnRH agonists may contribute to adverse cardiovascular outcomes. While additional clinical validation is required, prior Teverelix studies have not demonstrated significant cardiovascular safety signals to date.

Cardiovascular disease remains a leading cause of non-cancer mortality in prostate cancer, accounting for approximately 30% of deaths. The risk is further amplified during ADT, particularly among patients with pre-existing cardiovascular disease. Clinical and observational data indicate that such patients may experience a five- to six-fold higher incidence of major adverse cardiovascular events (MACE) when treated with GnRH agonists compared with GnRH antagonists.

Teverelix is being developed specifically for APC patients with objectively defined cardiovascular risk, including those with recent MACE or severe subclinical atherosclerosis, as measured by a coronary artery calcium (CAC) score greater than 400 in conjunction with elevated ASCVD risk.

Approximately 300,000 to 500,000 men in the United States are living with advanced prostate cancer, representing an estimated annual market opportunity exceeding US$4 billion.

The planned Phase 2b study is designed to evaluate durability of testosterone suppression, degree and consistency of FSH suppression, and cardiovascular safety. The study is intended to enable a registrational Phase 3 development pathway aligned with prior FDA guidance.

Clear Line of Sight to a Pivotal Phase 3 Program and Differentiated Labeling Strategy

Based on prior interactions with the U.S. Food and Drug Administration (FDA), Medicus has aligned on the development indication of “hormone therapy for advanced prostate cancer patients with increased cardiovascular risk.” The Company has defined a clear Phase 3 framework designed to evaluate sustained castration efficacy alongside cardiovascular outcomes.

This differentiated, CV-risk-focused labeling strategy has the potential to establish Teverelix as a new therapeutic backbone for patients in whom cardiovascular safety is a critical determinant of treatment choice.

In parallel, Medicus maintains a complete European clinical trial authorization framework under the Clinical Trial Information System (CTIS) for the APC program, supporting global development.

Medicus believes the Teverelix program is increasingly well positioned for strategic partnership discussions, particularly with organizations seeking differentiated late-stage oncology assets supported by a clear regulatory and labeling strategy.

Strategic Focus on Phase 2 De-Risking and Partnering

Medicus' development strategy is to advance select programs through Phase 2 proof-of-concept and pursue licensing or strategic partnerships with established pharmaceutical companies for late-stage development and commercialization.

The Company continues to assemble decision-grade clinical and regulatory data packages across its portfolio to support this partnering-focused model.

SkinJect™ Phase 2 Program on Track for Near-Term Data Readout and Partnering Readiness

In parallel, Medicus continues to advance SkinJect™, its proprietary dissolvable microneedle array platform delivering doxorubicin for the non-invasive treatment of basal cell carcinoma (BCC).

- Phase 2 enrollment (SKNJCT-003) completed with 90 patients across nine U.S. sites
- Topline decision-grade data expected in Q1 2026
- End-of-Phase 2 Food and Drug Administration ("FDA") meeting planned for the first half of 2026.

Previously disclosed positively trending interim findings demonstrated greater than 60% clinical clearance in an exploratory analysis conducted after more than 50% of patients of the then-targeted 60 patients in the study had been randomized. The findings of the interim analysis are preliminary and may or may not correlate with the findings of the study once completed.

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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.

SkinJect Inc., a wholly owned subsidiary of Medicus Pharma Ltd., is a development-stage life sciences company focused on commercializing a novel, non-invasive treatment for basal cell skin cancer using a patented dissolvable microneedle patch to deliver a chemotherapeutic agent to eradicate tumor cells. The Company completed a Phase 1 study (SKNJCT-001) in March of 2021, which met its primary objective of demonstrating safety and tolerability; the study also describes the efficacy of the investigational product doxorubicin-containing microneedle arrays (D-MNA), with six participants experiencing complete response on histological examination of the resected lesion. The Company is currently conducting a randomized, controlled, double-blind, multicenter clinical study (SKNJCT-003) in the United States and Europe. The Company has also commenced a randomized, controlled, double-blind, multicenter clinical study (SKNJCT-004) in the United Arab Emirates.

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.

In August 2025, the Company completed the acquisition of Antev, a UK-based late clinical stage biotech company, developing Teverelix, a next-generation gonadotrophin-releasing hormone (GnRH) antagonist, as a first-in-market product for cardiovascular high-risk advanced prostate cancer patients and patients with first acute urinary retention relapse (AURr) episodes due to enlarged prostate.

Unlike GnRH agonists, which can cause an initial surge in testosterone levels, Teverelix directly suppresses sex hormone production without this surge, potentially reducing cardiovascular risks. This mechanism is particularly beneficial for patients with existing cardiovascular conditions. Teverelix is formulated as a microcrystalline suspension, allowing for sustained release and a six-week dosing interval, which may improve patient compliance and outcomes.

In September 2020, Antev completed a Phase 1 clinical trial in which Teverelix was shown to be well tolerated with no dose-limiting toxicities and demonstrated rapid testosterone suppression. The study included 48 healthy male volunteers. In February

2023, Antev also completed a Phase 2a study in 50 patients with advanced prostate cancer (APC), where Teverelix achieved the primary endpoint of greater than 90% probability of castration levels of testosterone suppression (97.5%) but the secondary endpoint of maintaining this rate above 90% was not met, with the probability dropping to 82.5% by Day 42.

In January 2023, the U.S. Food and Drug Administration (FDA) reviewed the Phase 1 and Phase 2a data and provided written guidance on Antev's proposed Phase 3 trial design for Teverelix. This milestone supports the Company's clinical plans to develop Teverelix as a treatment for advanced prostate cancer patients with increased cardiovascular risk.

In December 2023, the FDA approved the Phase 2b study design in advanced prostate cancer covering 40 patients.

In November 2024, the FDA approved the Phase 2b study design in AURr covering 390 patients.

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.

Under the collaboration, Medicus and the GSA will jointly pursue the Expanded Access IND Program with the FDA to allow patients with multiple, recurrent, or inoperable basal cell carcinomas (BCCs) to access SkinJect under physician-supervised treatment protocols. The initiative aims to establish a framework for expanded access while collecting valuable real-world safety and tolerability data to inform future regulatory filings. It will also more tightly integrate patient community-led insights and data into the design, monitoring, and long-term development of SkinJect in this rare disease population.

In November 2025, the Company received full regulatory and ethical approvals in the United Kingdom to expand its ongoing Phase 2 clinical study (SKNJCT-003) evaluating D-MNA to non-invasively treat BCC of the skin. The approvals were issued by the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Research Authority (HRA) and the Wales Research Ethics Committee (WREC). The MHRA approval followed a comprehensive scientific review of the Investigational Medicinal Product Dossier (IMPD) and protocol. The WREC issued a favorable ethical opinion, and the HRA granted study-wide governance approval, confirming compliance with UK Good Clinical Practice and National Health Service capacity and capability standards.

In December 2025, the Company announced that it has successfully completed enrolment of 90 patients in the United States for Phase 2 clinical study (SKNJCT-003) evaluating D-MNA to non-invasively treat BCC of the skin. The Company expects to

release topline results for SKNJCT-003 in the first quarter of 2026 and secure an end-of-Phase 2 meeting with the FDA in the first half of 2026.

In December 2025, Medicus announced a non-binding letter of intent with Reliant AI Inc., a decision-intelligence company specializing in generative AI for the life sciences industry, to collaborate on the development of an AI-driven clinical data analytics platform. Subject to execution of definitive agreements, the platform is expected to support capital-efficient clinical development through data-driven dynamic clinical-site selection, patient stratification and enrollment forecasting. The initial phase of the collaboration is expected to support an upcoming Teverelix clinical study planned for 2026, with potential expansion into later-stage development programs in collaboration with a strategic partner.

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 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 expectation to release topline results for SKNJCT-003 in the first quarter of 2026 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, 2024 (the "Annual Report"), 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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