**Medicus Pharma Receives Positive FDA Feedback and Central IRB Approval for Optimized Phase 2 Teverelix® Novel Study in Acute Urinary Retention**

Regulatory and ethical-review milestones advance a capital-efficient Phase 2 study expected to enroll ~126 patients versus ~390 under the previously disclosed development plan

PHILADELPHIA, July 16, 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 therapeutic assets, today announced that it has received written feedback from the U.S. Food and Drug Administration ("FDA") and central Institutional Review Board ("IRB") approval, with modifications, for its optimized Phase 2 clinical study of Teverelix® in men following a first episode of acute urinary retention ("AUR").

The randomized, double-blind, placebo-controlled, multicenter study, designated **ANT-2111-02**, is a novel study designed to evaluate the pharmacodynamic effects of Teverelix DP, a long-acting gonadotropin-releasing hormone ("GnRH") antagonist, on prostate volume and urinary function in men following a first episode of AUR.

The Company submitted the optimized protocol to the FDA on April 2, 2026, under its existing Investigational New Drug ("IND") application for Teverelix. The redesigned study is expected to enroll approximately **126 patients** across the United States and Europe, compared with approximately **390 patients** contemplated under the Company's previously disclosed development plan, and is intended to generate an early pharmacodynamic signal while supporting dose optimization, route selection and future clinical development.

*"FDA's positive feedback and central IRB approval represent meaningful progress toward advancing our Teverelix Program," stated* ***Dr. Raza Bokhari, Medicus Executive Chairman and CEO****. "Acute urinary retention is a serious and distressing complication frequently associated with benign prostatic hyperplasia. By redesigning this study, we believe we have transformed the Teverelix development program into a substantially more efficient clinical strategy, reducing anticipated enrollment from approximately 390 patients to approximately 126 patients while preserving our ability to generate decision-grade clinical evidence. We believe this approach has the potential to accelerate clinical development, optimize capital allocation and generate the robust dataset needed to inform future FDA interactions, subsequent late-stage development, potential strategic partnering opportunities, and ultimately improve outcomes for patients suffering from this significant unmet medical need."*

**FDA Feedback Supports Advancement of the Optimized Protocol**

In its written response dated July 8, 2026, the FDA provided seven comments and recommendations concerning protocol implementation, safety monitoring and protocol clarification. The recommendations include:

- Aligning contraception and pregnancy reporting requirements with the one-year study duration.
- Maintaining blinding for injection-site assessments;
- Documenting changes in concomitant alpha-blocker therapy.
- Collecting subjects' race in addition to age and ethnicity.
- Clarifying investigator discretion in evaluating injection-site induration; and
- Revising the wording of a secondary composite endpoint to ensure that its component criteria are interpreted as intended.

Importantly, the Company believes the FDA's recommendations are operational in nature, readily addressable through targeted protocol and study-document amendments, and do not require changes to the study's scientific rationale, patient population, treatment arms, primary endpoint or planned interim analysis. Medicus intends to incorporate the FDA's recommendations into the protocol and related study documentation as it advances toward study initiation.

**Central IRB Approval Received**

***Advarra***, the study's Central IRB, approved the ANT-2111-02 protocol with modifications on June 18, 2026, with the approval period extending through June 18, 2027. Approved documentation includes the clinical protocol, informed consent forms, the Teverelix Investigator's Brochure, patient recruitment materials and patient-reported outcome instruments. The requested IRB modifications relate to the informed consent templates.

The Central IRB approval applies to the study protocol. Each participating principal investigator and clinical site must complete site-specific submissions and receive local authorization before initiating patient enrollment.

**Optimized Phase 2 Study Designed to Generate Decision-Grade Clinical Evidence:**

ANT-2111-02 is a randomized, double-blind, placebo-controlled, multicenter Phase 2 clinical study evaluating Teverelix for the prevention of recurrent acute urinary retention in men following a first episode of acute urinary retention secondary to benign prostatic hyperplasia.

The optimized Phase 2 study is expected to enroll approximately **126 patients-approximately one-third of the enrollment contemplated under the Company's previously disclosed development plan-**and will evaluate optimized intramuscular

and subcutaneous Teverelix regimens versus matched placebo controls in men following a first episode of acute urinary retention secondary to benign prostatic hyperplasia.

The study incorporates:

- A mechanism-driven primary endpoint evaluating reduction in total prostate volume.
- Prospective evaluation of recurrent acute urinary retention.
- Assessment of urinary function, including maximum urinary flow rate (Qmax) and post-void residual volume (PVR);
- Protocol-defined treatment failure and need for BPH-related medical or surgical intervention.
- Comprehensive pharmacodynamic, endocrine and safety assessments.
- Longitudinal evaluation of durability of treatment effect; and
- A pre-specified interim analysis designed to optimize dose selection, route of administration and subsequent clinical development.

The Company believes this integrated study design efficiently addresses multiple critical development questions within a single clinical trial while maintaining rigorous scientific and regulatory standards. **If successfully executed, the optimized study is expected to generate one of the most comprehensive Phase 2 clinical datasets assembled for Teverelix, supporting future regulatory discussions, clinical development decisions and strategic partnering opportunities.**

The Company is working with its regulatory, clinical and contract-research partners to incorporate the FDA and IRB comments, finalize participating clinical sites and complete the remaining study-start-up activities.

Following incorporation of the FDA recommendations and completion of study start-up activities, the Company intends to continue progressing site activation while continuing discussions with FDA regarding opportunities to further optimize the overall clinical development and potential registrational strategy for the program. Medicus expects to provide additional guidance regarding study activation and anticipated enrollment timing following completion of these activities.

The optimized ANT-2111-02 study builds upon clinical experience from more than **400 patients** previously treated with Teverelix across multiple clinical studies and reflects extensive scientific, clinical and regulatory evaluation undertaken by the Company together with internationally recognized experts in urology, clinical development and regulatory science.

**About Acute Urinary Retention**

Acute urinary retention is the sudden inability to urinate and is among the most serious complications of benign prostatic hyperplasia and is considered a medical emergency frequently results in emergency catheterization, recurrent healthcare utilization and progression to minimally invasive or surgical intervention.

Although currently available medical therapies primarily manage lower urinary tract symptoms associated with BPH, there remains an important unmet medical need for therapies specifically intended to reduce recurrence following an initial episode of acute urinary retention.

Medicus believes Teverelix has the potential to establish a new treatment paradigm by addressing one of the underlying biological drivers of recurrent AUR rather than simply managing its consequences.

**About Teverelix®**

Teverelix® is a next-generation, long-acting gonadotropin-releasing hormone (GnRH) antagonist being developed across multiple hormone-dependent indications, including recurrent acute urinary retention associated with benign prostatic hyperplasia, advanced prostate cancer in patients with elevated cardiovascular risk, and selected women's health indications.

**For further information contact:**

Carolyn Bonner, President and Chief Financial Officer
(610) 636-0184
cbonner@medicuspharma.com

Anna Baran-Djokovic, SVP Investor Relations
(305) 615-9162
adjokovic@medicuspharma.com

***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 therapeutic assets. The Company is actively engaged in multiple countries across three continents.*

*The Company's current key therapeutic 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.*

***Teverelix®, a next-generation GnRH antagonist,*** *is a product under clinical development for cardiovascular high-risk advanced prostate cancer patients and patients with acute urinary retention relapse (AURr) episodes due to enlarged prostate, and endometriosis.*

*Medicus' strategy is to advance select programs through Phase 2 proof-of-concept, key clinical and regulatory inflection points that substantially reduce development risk and increase attractiveness to potential pharmaceutical partners. By generating decision-grade clinical, regulatory and operational datasets, the Company seeks to create opportunities for strategic collaborations, regional licensing transactions and broader commercialization partnerships with established pharmaceutical companies. As data matures across its programs, Medicus intends to continue building differentiated development packages designed to maximize asset value while maintaining capital efficiency and development focus.*

***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 development of SkinJect® and the potential benefits thereof for those suffering with Gorlin Syndrome, the development of Teverelix® and expectations concerning, and future outcomes relating to, the development, advancement and commercialization of Teverelix® for AURr, cardiovascular high-risk advanced prostate cancer, women's health indications like endometriosis, and the potential market opportunities related thereto, the receipt of, and the interpretation and implications of, the FDA's written feedback and the central IRB approval for the ANT-2111-02 study and the Company's response to such feedback; the Company's expectations regarding the Phase 2 study, the timing and results thereof, including the number patients to be enrolled therein; the Company's expectations regarding the generation of an early pharmacodynamic signal, decision-grade clinical evidence and a comprehensive Phase 2 dataset for Teverelix®, and the potential to accelerate clinical development, optimize capital allocation and support dose optimization and route selection; the potential for Teverelix® to establish a new treatment paradigm for recurrent AUR; and potential strategic partnering opportunities; 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 of SkinJect®. 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.*

MEDICUS PHARMA