MannKind Shares FUROSCIX® Business Updates

12/23/25

- *FDA approves FUROSCIX® for use in pediatric patients weighing 43kg or above*
- *USPTO issues five patents for FUROSCIX ReadyFlow ™ Autoinjector*

WESTLAKE VILLAGE, Calif. and BURLINGTON, Mass., Dec. 23, 2025 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today announced two business updates—approval of the FUROSCIX® (furosemide) On-body Infusor for pediatric patients and issuance of additional intellectual property protection for the investigational-stage FUROSCIX ReadyFlow ™ Autoinjector, which is currently under review by the U.S. FDA.

FUROSCIX Expanded Treatment Options for Appropriate Pediatric Patients
The U.S. Food and Drug Administration (FDA) has approved a supplemental New Drug Application (sNDA) for FUROSCIX® (furosemide) On-body Infusor, expanding the indication of this product to include pediatric patients weighing 43 kg or more. FUROSCIX was previously approved for the treatment of edema associated with chronic heart failure (CHF) and chronic kidney disease (CKD) in adults. This additional approval fulfills all post-marketing requirements outlined in the original approval letter under the Pediatric Research Equity Act.

"We are pleased to make FUROSCIX available to the pediatric population, a highly specific patient group, offering a convenient option outside the hospital setting for those who meet the weight criteria," said Dr. Ajay Ahuja, Chief Medical Officer of MannKind Corporation.

Five New U.S. Patents Provide Protection to FUROSCIX ReadyFlow Autoinjector
The U.S. Patent and Trademark Office (USPTO) issued five patents with claims that protect the FUROSCIX ReadyFlow Autoinjector. These patents cover the high-concentration liquid compositions of furosemide and associated methods of treatment potentially through 2040, further reinforcing MannKind's intellectual property position around this innovative drug-device combination. The patents would be listed in the FDA's Orange Book, if the FUROSCIX ReadyFlow Autoinjector is approved by the FDA.

The newly issued patents complement previously issued patents supporting FUROSCIX and the FUROSCIX ReadyFlow Autoinjector, creating a robust IP portfolio that is designed to protect the formulation and delivery approach for years to come.

FUROSCIX ReadyFlow Autoinjector Could Transform Care from Hours to Seconds
MannKind recently announced that the FDA accepted for review its sNDA for the FUROSCIX ReadyFlow Autoinjector for the treatment of edema in adults with CHF or CKD. The application has been assigned a Prescription Drug User Fee Act (PDUFA) target action date of July 26, 2026.

If approved, the FUROSCIX ReadyFlow Autoinjector would deliver an IV-equivalent diuretic dose (subcutaneous furosemide injection 80 mg/mL) in under 10 seconds, providing a new option for patients with CHF or CKD to manage fluid buildup episodes from the convenience of their home rather than in a hospital setting. The FDA-approved FUROSCIX On-body Infusor was approved in 2022 for the treatment of edema in adult patients with chronic heart failure and, in 2025, for adult patients with chronic kidney disease in 2025.

"FUROSCIX ReadyFlow Autoinjector has the potential to redefine how patients manage fluid overload episodes," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "By delivering an IV-equivalent diuretic dose in seconds from the comfort of home, this innovation, if approved, could significantly reduce hospital visits, improve quality of life, and lower healthcare costs—creating meaningful value for patients, providers, and payers alike."

About FUROSCIX
FUROSCIX® (furosemide injection), 80 mg/10 mL for subcutaneous use is indicated for the treatment of edema (i.e., congestion, fluid overload, or hypervolemia) in pediatric patients who weigh at least 43 kg and adult patients with chronic heart failure or chronic kidney disease, including the nephrotic syndrome.

IMPORTANT SAFETY INFORMATION
FUROSCIX is contraindicated in patients with anuria and in patients with a history of hypersensitivity to furosemide, any component of the FUROSCIX formulation, or medical adhesives.

Furosemide may cause fluid, electrolyte, and metabolic abnormalities, particularly in patients receiving higher doses, patients with inadequate oral electrolyte intake, and in elderly patients. Serum electrolytes, CO_2, BUN, creatinine, glucose, and uric acid should be monitored frequently during furosemide therapy.

Excessive diuresis may cause dehydration and blood volume reduction with circulatory collapse and possibly vascular thrombosis and embolism, particularly in elderly patients.

Furosemide can cause dehydration and azotemia. If increasing azotemia and oliguria occur during treatment of severe progressive renal disease, discontinue furosemide.

Cases of tinnitus and reversible or irreversible hearing impairment and deafness have been reported with furosemide. Reports usually indicate that furosemide ototoxicity is associated with rapid injection, severe renal impairment, the use of higher than recommended doses, hypoproteinemia or concomitant therapy with aminoglycoside antibiotics, ethacrynic acid, or other ototoxic drugs.

In patients with severe symptoms of urinary retention (because of bladder emptying disorders, prostatic hyperplasia, urethral narrowing), the administration of furosemide can cause acute urinary retention related to increased production and retention of urine. These patients require careful monitoring, especially during the initial stages of treatment.

Contact with water or other fluids and certain patient movements during treatment may cause the On-body Infusor to prematurely terminate infusion. Ensure patients can detect and respond to alarms.

The most common adverse reactions with FUROSCIX administration in clinical trials were site and skin reactions including erythema, bruising, edema, and injection site pain.

Please see the full **Prescribing Information** (**https://www.furoscix.com/wp-content/uploads/prescribing-information.pdf**) and **Instructions for Use** (**https://www.furoscix.com/wp-content/uploads/instructions-for-use.pdf**).

About MannKind
MannKind Corporation (Nasdaq: MNKD) is a biopharmaceutical company dedicated to transforming chronic disease care through innovative, patient-centric solutions. Focused on cardiometabolic and orphan lung diseases, we develop and commercialize treatments that address serious unmet medical needs, including diabetes, pulmonary hypertension, and fluid overload in heart failure and chronic kidney disease.

With deep expertise in drug-device combinations, MannKind aims to deliver therapies designed to fit seamlessly into daily life.

Learn more at mannkindcorp.com.

Forward-Looking Statements
This press release contains forward-looking statements that involve risks and uncertainties, including statements about a potential regulatory action date, statements regarding the potential duration of patent protection and statements regarding the potential benefits of the administration of furosemide via an autoinjector for providers, patients and payors. Words such as “believes”, “anticipates”, “plans”, “expects”, “intends”, “will”, “goal”, “potential” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon MannKind’s current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, the risk that issues that develop in the review by the FDA may subject us to unanticipated delays or prevent us from obtaining marketing approval, the risk that we may be unable to protect our proprietary rights as well as other risks detailed in MannKind’s filings with the Securities and Exchange Commission, including under the “Risk Factors” heading of its Annual Report on Form 10-K for the year ended December 31, 2024, and subsequent periodic reports on Form 10-Q and current reports on Form 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and MannKind undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.

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