MannKind Announces U.S. FDA Accepts for Review its Supplemental New Drug Application (sNDA) of FUROSCIX ReadyFlow™ Autoinjector for the Treatment of Edema in Adults with Chronic Heart Failure or Chronic Kidney Disease

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- *If approved, ReadyFlow Autoinjector would deliver an IV-equivalent diuretic dose (subcutaneous furosemide injection 80 mg/ml) in under 10 seconds*
- *Would potentially provide a cost-effective and convenient option to address episodes of fluid buildup at home, benefiting patients, providers and payors*
- *PDUFA target action date of July 26, 2026*

WESTLAKE VILLAGE, Calif. and BURLINGTON, Mass., Dec. 01, 2025 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today announced that the U.S. Food and Drug Administration (FDA) has accepted the sNDA seeking approval for FUROSCIX ReadyFlow™ Autoinjector (SCP-111), developed to deliver a subcutaneous furosemide injection in under 10 seconds as an investigational alternative to the FDA-approved FUROSCIX® (furosemide) On-body Infusor for treatment of edema in adult patients with chronic heart failure (CHF) or chronic kidney disease (CKD). The application has been assigned a Prescription Drug User Fee Act (PDUFA) target action date of July 26, 2026.

“The FUROSCIX ReadyFlow Autoinjector marks a key milestone in expanding patient options and improving care. By delivering treatment in under 10 seconds, the ReadyFlow Autoinjector has the potential to transform how adults with chronic heart failure or chronic kidney disease manage episodes of fluid buildup—providing faster relief, reducing hospital admissions, and lowering overall healthcare costs,” said Michael Castagna, PharmD, Chief Executive Officer at MannKind Corporation. “We are excited about the opportunity to bring this innovation forward and empower patients with greater convenience and control in their treatment journey.”

If approved, FUROSCIX ReadyFlow Autoinjector would provide 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 for adult patients with edema in chronic heart failure in 2022 and in chronic kidney disease in 2025. The ReadyFlow Autoinjector would reduce administration time from five hours to under 10 seconds.

The sNDA is supported by positive study results announced in August 2024. Furosemide via the ReadyFlow Autoinjector demonstrated a bioavailability of 107.3% (90% CI: 103.9 – 110.8), achieving the 90% confidence interval limit of 80 to 125 percent. Additionally, participants who utilized ReadyFlow Autoinjector had similar urine output, urinary sodium excretion and urinary potassium excretion at 6, 8, and 12 hours compared to IV furosemide, and was generally well tolerated with respect to injection site pain.

The study was an open-label, single-center, single-dose, randomized, two-way crossover study in 21 healthy volunteers, ranging in age from 45 to 80. Each subject completed the screening, baseline, treatment, and follow-up phases. Subjects were randomly assigned in a 1:1 ratio to one of two treatment sequences (IV furosemide followed by furosemide via the ReadyFlow Autoinjector, or vice versa).

About FUROSCIX

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, 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 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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Source: MannKind