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MannKind Announces FDA Approval of Furoscix ReadyFlow™, the First and Only Autoinjector Delivering IV-Equivalent Diuretic Therapy for the Treatment of Edema in Adults with Heart Failure or Chronic Kidney Disease

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- *Transformative delivery option that may support earlier management of worsening fluid overload with a self-administered option designed for use outside the hospital setting*
- *Furosemide is administered subcutaneously in under 10 seconds, with a therapeutic onset of action in minutes*
- *Provides an 80 mg/mL furosemide dose in a single administration in under 10 seconds*
- *Symptom relief may begin in an hour or less*
- *Conference call and webcast scheduled for July 24 at 9:00 a.m. ET*

WESTLAKE VILLAGE, Calif., and BOSTON, July 24, 2026 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD),** a biopharmaceutical company dedicated to transforming chronic disease care through innovative, patient-centric solutions for cardiometabolic and orphan lung diseases, today announced that the U.S. Food and Drug Administration (FDA) has approved Furoscix ReadyFlow™ (furosemide injection) for the treatment of edema (fluid overload) in adults with heart failure (HF) or chronic kidney disease (CKD).

Furoscix ReadyFlow is an at-home treatment option designed to help adults with heart failure or chronic kidney disease address fluid overload earlier, before worsening symptoms may lead to emergency department visits, hospitalization, or readmission. As the first and only autoinjector delivering subcutaneous furosemide with IV-equivalent exposure (based on comparisons of AUC and PD endpoints), Furoscix ReadyFlow provides a full 80 mg/mL dose in a simple, patient-friendly format administered in under 10 seconds. The therapy is absorbed into the bloodstream, and symptom relief may begin in an hour or less. Together, these attributes may help expand opportunities for earlier intervention and extend IV-equivalent furosemide exposure beyond the hospital for appropriate patients across outpatient, post-discharge and home-based care settings.

"Too often, patients living with heart failure or chronic kidney disease find themselves caught in a cycle of worsening fluid overload that can disrupt daily life and lead to ER visits and hospitalization," said Hunter Champion, MD, PhD, Emory University Healthcare Network and Director of the Heart Failure and Pulmonary Hypertension program at Southeastern Cardiology Associates in Columbus, Georgia. "An at-home option that delivers similar IV-equivalent furosemide exposure through a simple autoinjector gives clinicians an important new tool to intervene as soon as signs and symptoms of fluid overload appear helping appropriate patients manage congestion outside the hospital setting while reducing the disruption and burden associated with hospital-based treatment."

Heart failure affects approximately 6.7 million adults in the United States and is projected to increase to more than 8 million by 2030. Fluid overload is a primary driver of worsening symptoms and one of the most common reasons patients with heart failure or chronic kidney disease require emergency department visits, hospitalization, or readmission. Chronic kidney disease frequently coexists with heart failure and can further complicate fluid management, increasing the risk of recurrent events. Heart failure remains one of the costliest chronic conditions in the United States, with hospitalizations accounting for approximately 80% of heart failure-related healthcare costs. By 2030, heart failure costs in the United States are expected to be at least $70 billion per year.
Together, these dynamics underscore the need for outpatient treatment options that can help appropriate patients receive timely intervention for worsening fluid overload before hospital-based care may become necessary.

"The approval of Furoscix ReadyFlow marks an important milestone for patients living with heart failure or chronic kidney disease who experience fluid overload," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "By combining IV-equivalent diuretic performance with the simplicity of an autoinjector, Furoscix ReadyFlow has the potential to advance how fluid overload is managed outside traditional care settings and reach appropriate patients at different intervention points—from the onset of worsening symptoms and, when hospitalization cannot be avoided, through the transition home. We believe this represents a meaningful step forward for patients, practitioners, payers and hospitals—helping ease fluid burden for patients while reducing pressure on an increasingly burdened healthcare system."

The FDA approval is supported by positive clinical data demonstrating that Furoscix ReadyFlow achieved its primary pharmacokinetic endpoint. The study also demonstrated equivalent urine output, sodium excretion and potassium excretion at 6, 8 and 12 hours compared to IV furosemide. Furoscix ReadyFlow was generally well tolerated, with a safety profile consistent with known effects of oral and intravenous furosemide.

The FDA-approved Furoscix (furosemide injection) delivered via an On-body infusor is currently available and was approved for adult patients with edema in HF in 2022 and CKD in 2025. Furoscix ReadyFlow is expected to be commercially available in the United States by the end of August 2026, offering solutions for cardiologists, nephrologists, outpatient heart failure clinics and integrated delivery networks (IDNs). The Furoscix ReadyFlow autoinjector will reduce administration time from five hours with the currently available On-body infusor to 10 seconds or less.

MannKind is committed to helping people access the medicines they are prescribed and minimizing barriers to care. Furoscix Direct provides dedicated support for patients, caregivers and healthcare providers seeking access and coverage information at (855) FUROSCIX (387-6724).

Management of the Company will host a conference call to discuss the approval at 9:00 a.m. ET on July 24 2026. Presenting from the Company will be its Chief Executive Officer, Michael Castagna and Chief Medical Officer Ajay Ahuja, MD.

To view and listen to the webcast, visit MannKind's website at https://investors.mannkindcorp.com/events-and-presentations. A replay will also be available on MannKind's website for approximately 90 days.

What is Furoscix® (furosemide injection) for subcutaneous use in the stomach area (abdomen)?
Furoscix is a prescription medicine used to treat fluid buildup, which can cause congestion or swelling (also known as edema), in adult patients with chronic heart failure or chronic kidney disease.

Furoscix should be replaced with oral diuretics as directed by a healthcare provider. Follow the instructions provided by your physician when taking Furoscix.

IMPORTANT SAFETY INFORMATION

Before taking Furoscix, read the instructions for Use and tell your healthcare provider about all your medical conditions, including if you have liver problems, trouble urinating, are allergic to furosemide or any of the ingredients in Furoscix.

What are the possible side effects of Furoscix?
Dehydration: Furoscix can cause you to lose excess water and electrolytes. Symptoms of excess water and electrolyte loss include dry mouth, increased thirst, muscle pains or cramps, decreased urine output or urine more yellow than normal, headache, dry skin, nausea or vomiting. Your healthcare provider may check your electrolytes while receiving Furoscix.

Low Blood Pressure: Furoscix may cause your blood pressure to decrease temporarily. You may feel lightheaded or dizzy, particularly when you stand up. Getting up slowly may help.

High Blood Sugar: If you have diabetes mellitus, Furoscix may increase blood glucose levels.

Loss of Hearing: Furoscix can cause ringing in your ears. Tell your healthcare provider if you have trouble hearing while taking Furoscix.

Incomplete Dosing: When using the Furoscix ReadyFlow, if the viewing window does not turn completely yellow, or if you lift the Furoscix ReadyFlow off your skin too early, you may not receive a full dose. This could cause the medicine to not work as well as it should. If this happens call your healthcare provider for more instructions. Do not use another Furoscix ReadyFlow unless instructed to do so by your healthcare provider.

Your skin may be more sensitive to sunlight while taking Furoscix.

The most common side effects with Furoscix are administration site and skin reactions such as bruising, redness, swelling and administration site pain.

Call your healthcare provider for medical advice about side effects. You may report side effects to MannKind at 1-877-322-6505 or to the FDA at 1-800-FDA-1088.

For more information about Furoscix, please see the full Prescribing Information (www.furoscix.com/assets/docs/uploads/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
Forward-looking statements that are not statements of historical fact are forward-looking statements that involve risks and uncertainties. These statements include, without limitation, statements regarding opportunities to manage fluid overload at different intervention points or outside of a traditional hospital setting as well as the potential of Furoscix to ease fluid burden for patients while reducing pressure on the healthcare system. 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 MannKind's products may only achieve a limited degree of commercial success, and other risks detailed in MannKind's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2025 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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Photos accompanying this announcement are available at
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Furoscix ReadyFlow [prototype]

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