NEWS RELEASE

Ligand Partner SQ Innovation Receives FDA Approval for Lasix® ONYU, an At-Home Treatment for Edema in Heart Failure Patients

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Second-generation delivery device offers cost-effective alternative to hospital care benefiting patients, providers, and payors

Lasix ONYU is the 17th Captisol-enabled™ approved product

JUPITER, Fla., Oct. 09, 2025 (GLOBE NEWSWIRE) -- Ligand Pharmaceuticals Incorporated (Nasdaq: LGND) today announced that its partner SQ Innovation Inc. has received approval from the U.S. Food and Drug Administration (FDA) for Lasix® ONYU (furosemide injection), a novel drug-device combination for the treatment of edema (due to fluid overload) in adult patients with chronic heart failure. Lasix ONYU can be administered subcutaneously outside the healthcare setting for selected patients, as prescribed by a clinician, without the need for a healthcare professional to administer the drug.

Lasix ONYU provides a novel high-concentration formulation of furosemide combined with a state-of-the-art small Infusor for treatment at home. The innovative design features a reusable unit that can be used for 48 treatments and a plastic sterile single-use unit that is discarded after treatment. Captisol®, a Ligand technology, is a key part of the Lasix ONYU novel, high- concentration formulation of furosemide 80mg/2.67mL (30mg/mL). There are now seventeen approved products formulated with Captisol demonstrating its ability to optimize the solubility, stability, and bioavailability of medicines. Captisol can be

used across multiple routes of administration including intravenous, intramuscular, oral, and subcutaneous.

“Lasix ONYU has the potential to benefit millions of heart failure patients who would otherwise receive treatment with IV diuretics in the hospital,” said Todd Davis, CEO of Ligand. “Our partnership with SQ Innovation further demonstrates the powerful role Captisol plays in the development and delivery of new medicines. By optimizing drug solubility, stability, and bioavailability, we are paving the way for companies to develop safer and more effective therapies that can change patient lives for the better.”

Episodes of edema due to fluid overload are common in patients with heart failure. This condition commonly leads to hospitalization, where patients are treated with IV diuretics, most commonly furosemide. Lasix ONYU offers similar diuresis when compared to IV treatment but can now be used outside of a healthcare setting. About 6.7 million Americans suffer from heart failure, with the prevalence expected to rise to 8.7 million by 2030. Heart failure is a leading cause of hospitalizations for individuals aged 65 and older with approximately 1.2 million hospitalizations a year.[1]

“In our formulation research we considered all solubility enhancers widely accepted in pharmaceutical products for human use and discovered Captisol was the only one that allowed us to achieve a room temperature stable pH-neutral product at 30mg/mL,” said Pieter Muntendam, MD, founder, president, and CEO of SQ Innovation. “The Captisol laboratories helped us optimize the composition of Lasix ONYU and provided extensive preclinical safety and regulatory expertise. They were a trusted partner every step of the way.”

Ligand entered into exclusive worldwide Captisol license and supply agreements with SQ Innovation for high-concentration furosemide formulation in 2019. Under the terms of the agreements, Ligand will supply SQ Innovation Captisol for the pharmaceutical formulation of Lasix ONYU and is entitled to milestone payments, a low-single-digit royalty, and revenue from material sales.

SQ Innovation expects Lasix ONYU to be available in the fourth quarter of 2025. For important safety information and full prescribing information go to **www.lasix-onyu.com**.

About Captisol®

Captisol, a Ligand technology, is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility, stability, and bioavailability of drugs. Captisol was invented and initially developed by scientists in the laboratories of Dr. Valentino Stella, University Distinguished Professor at the University of Kansas' Higuchi Biosciences Center, for specific use in drug development and formulation. This unique technology has enabled several FDA-approved products, Amgen's Kyprolis®, Baxter's

Nexterone®, Acrotech Biopharma's Evomela®, Gilead's Veklury®, and Merck's Noxafil®. More information is available at **www.captisol.com.**

About Ligand Pharmaceuticals

Ligand is a biopharmaceutical company enabling scientific advancement through supporting the clinical development of high-value medicines. Ligand does this by providing financing, licensing our technologies or both. Our business model seeks to generate value for stockholders by creating a diversified portfolio of biotech and pharmaceutical product revenue streams that are supported by an efficient and low corporate cost structure. Our goal is to offer investors an opportunity to participate in the promise of the biotech industry in a profitable and diversified manner. Our business model is based on funding programs in mid- to late-stage drug development in return for economic rights, purchasing royalty rights in development stage or commercial biopharmaceutical products and licensing our technology to help partners discover and develop medicines. We partner with other pharmaceutical companies to attempt to leverage what they do best (late-stage development, regulatory management and commercialization) in order to generate our revenue. We operate two infrastructure-light royalty generating technology IP platform technologies. Our Captisol® platform technology is a chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Our NITRICIL™ platform technology facilitates tunable dosing, permitting an adjustable drug release profile to allow proprietary formulations that target a broad range of indications. We have established multiple alliances, licenses and other business relationships with the world's leading pharmaceutical companies including Amgen, Merck, Pfizer, Jazz, Gilead Sciences and Baxter International. For more information, please visit **www.ligand.com**. Follow Ligand on **X** and **LinkedIn**.

We use our investor relations website and X as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor our website and our X account, in addition to following our press releases, SEC filings, public conference calls and webcasts.

Forward-Looking Statements

This news release contains forward-looking statements by Ligand that involve risks and uncertainties and reflect Ligand's judgment as of the date of this release. Words such as "plans," "believes," "expects," "anticipates," and "will," and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include: the timing of commercial launch of Lasix ONYU; the potential that Lasix ONYU can benefit patients who would otherwise be treated with IV diuretics in the hospital; and the potential market size of patients who can be treated with Lasix ONYU. Actual events or results may differ from Ligand's or its partner's expectations due to risks and uncertainties inherent in Ligand's and its partner's business, including, without limitation: SQ Innovation may not be able to successfully

commercialize Lasix ONYU which will depend on a number of factors including coverage and reimbursement levels from governmental authorities and health insurers as well as market acceptance by healthcare providers; the market size for Lasix ONYU may be smaller than estimated; Ligand is dependent on SQ Innovation for the commercialization of Lasix ONYU; and other risks described in Ligand's prior press releases and filings with the Securities and Exchange Commission available at **www.sec.gov**. Ligand disclaims any intent or obligation to update these forward-looking statements beyond the date of this release. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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[1] HF STATS 2025: Heart Failure Epidemiology and Outcomes Statistics An Updated 2025 Report from the Heart Failure Society of America. J Card Fail. 2025 Aug 29:S1071-9164(25)00326-4. doi: 10.1016/j.cardfail.2025.07.007. Epub ahead of print. PMID: 40987671.

Source: Ligand Pharmaceuticals