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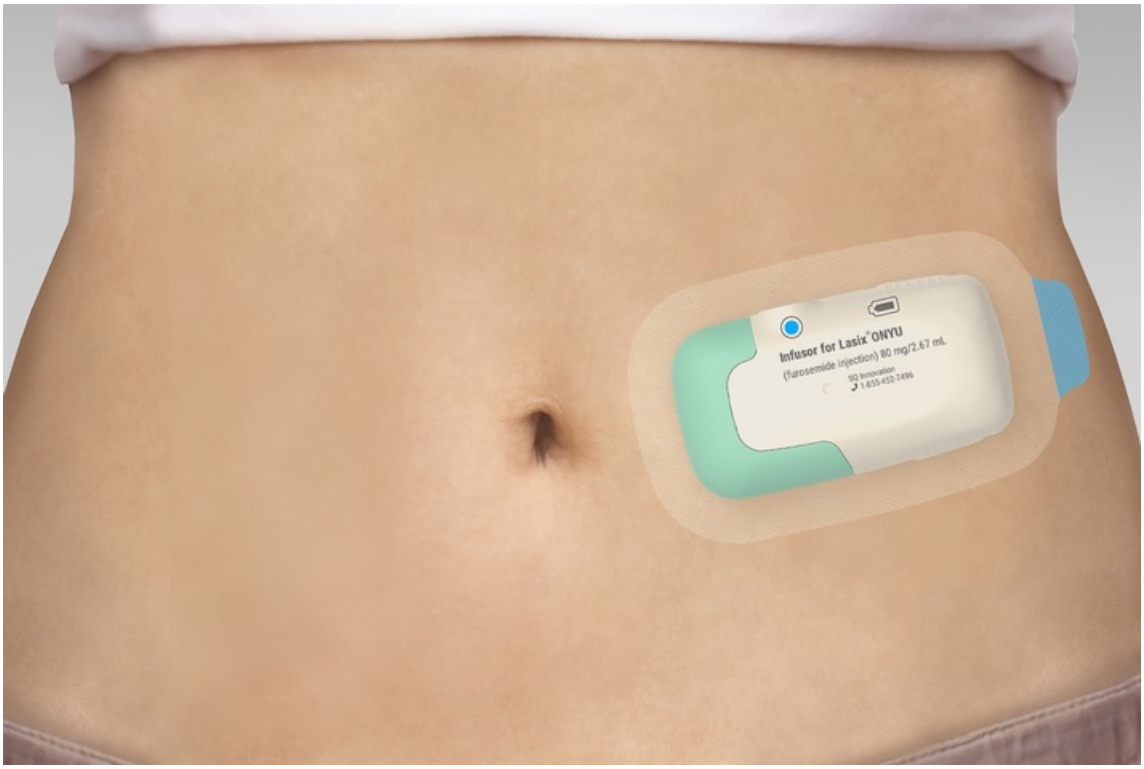
Gerresheimer: FDA grants Tentative Approval of SQ Innovation's Lasix® ONYU*



Düsseldorf (ots) -

- Innovative combination product of furosemide and on-body device
- Ready-to-market device designed, developed and manufactured by Gerresheimer
- Patented device technology for precise administration

Gerresheimer, an innovative system and solution provider and a global partner for the pharma, biotech and cosmetics industries, announces that the US Food and Drug Administration (FDA) granted SQ Innovation Tentative Approval for Lasix ONYU for the home treatment of fluid overload in congestive heart failure. Lasix ONYU is a combination product consisting of a novel high-concentration formulation of the diuretic furosemide and the Gerresheimer on-body drug delivery device. Tentative Approval indicates here that Lasix ONYU has met the regulatory standards for quality, safety and efficacy required for approval in the United States. Full approval was precluded because the FDA had granted market exclusivity in the USA for a competing product until October 2025. SQ Innovation will seek full approval in the U.S. after the expiration of the regulatory exclusivity period. First products of Lasix ONYU are now expected to be available on the market by the end of 2025. The Tentative Approval of the combination product underscores Gerresheimer's innovative strength and the market readiness of the Gerresheimer on-body drug delivery device.

"The FDA's Tentative Approval is a testament to our product and the people and partners who have contributed to this great endeavor, especially the Gerresheimer team", says Pieter Muntendam, MD, Founder, President and CEO of SQ Innovation. "It is an important milestone. We look forward to commercializing this highly innovative combination product as soon as we receive final approval with the aim to improve patients' quality of life and reduce healthcare costs for the elderly."

"The regulatory authority's decision underlines the market readiness of our on-body drug delivery device," said Dietmar Siemssen, CEO of Gerresheimer AG. "It also clearly demonstrates our expertise as an innovative solution provider for our customers, from product design to regulatory submission and large-scale manufacturing. With our on-body devices for both small molecule drug formulations and large molecule biologics we can partner with our customers to address the global megatrend of home treatment, while also providing connectivity to remote therapeutic monitoring platforms."

Device based on Gerresheimer's innovative micropump technology

The cartridge-based infusor was designed and developed by Gerresheimer based on its proprietary infusor platform for subcutaneous drug delivery. The core technology is an innovative micropump which enables controlled, precise administration of a drug product according to a defined therapy regimen.

Designed with patient comfort and the environment in mind

The lightweight, compact device is patched onto the patient's body, making it comfortable for the patient to wear while the drug is gently infused. The user-friendly design features a simple one-button operation with automatic needle insertion and retraction.

The Lasix ONYU infusor has two components, a reusable electromechanical component, and a single-use sterile disposable component that is in contact with the drug solution and the body. The reusable component, which is rated for delivery of 48 treatments with diuretic furosemide, is recyclable. Because only the disposable unit requires sterilization, radiation can be used instead of chemical sterilization, and no electronic components end up in medical waste. This two-component concept was developed in line with Gerresheimer's EcoDesign principles, which aim to increase product lifespan and reduce waste.

Reducing total cost of care and improving patients' quality of life

The combination product Lasix ONYU also opens up possibilities to reduce the total cost of care. The two-component design results in a lower cost per treatment, because only the disposable part of the device needs to be replaced. Most importantly, the infusor allows for home treatment, reducing the length of hospital stay or avoiding the need for hospitalization for intravenous diuretic administration altogether.

First products expected to be available end of 2025

In addition to Gerresheimer's role in design and development Gerresheimer also manages production of the device as a full-service solution provider. The disposable unit for the infusor is, for example, produced at the Gerresheimer facility in Wackersdorf, Germany, on a high-capacity semi-automated line.

SQ Innovation will seek full approval in the U.S. after the competitive product's regulatory exclusivity period expires in October 2025. First products of Lasix ONYU are now expected to be available on the market by the end of 2025.

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Medieninhalte

Lasix ONYU is a combination product consisting of a novel high-concentration formulation of the diuretic furosemide and the Gerresheimer on-body drug delivery device. / More information via ots and www.presseportal.de/en/nr/9072 / The use of this image for editorial purposes is permitted and free of charge provided that all conditions of use are complied with. Publication must include image credits.

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