

Sequana Medical alfapump® System Highlighted at SIR EDGE 2025 Conference

Ghent, Belgium – 14 October 2025 – Sequana Medical NV (Euronext Brussels: SEQUA (the “Company” or “Sequana Medical”)), a pioneer in the treatment of drug-resistant fluid overload in liver disease, heart failure and cancer, today announced that the **alfapump** System was highlighted in a presentation at the Society of Interventional Radiology’s SIR EDGE 2025 conference in San Diego. The presentation titled “Not the Alpha Male, the Alfapump!” showcased the clinical impact and innovative approach of the **alfapump** technology.

Dr. Ziv Haskal, Professor of Radiology and Medical Imaging and Interventional Radiology at the University of Virginia, and presenter at the conference, commented: “The **alfapump** represents a paradigm shift in how we approach refractory ascites unsuitable for TIPS. The implantable **alfapump** does exactly that by providing continuous, automated ascites removal that liberates patients from the endless painful paracentesis procedures.”

Dr. Gijs Klarenbeek, Chief Medical Officer of Sequana Medical, continued: “The presentation at SIR EDGE captured what makes the **alfapump** so compelling for both physicians and patients, and we are delighted that the **alfapump** was featured at one of the premier clinical forums for interventional radiology. As we execute our U.S. commercial launch, we’ll continue our goal of showing interventional radiologists how the **alfapump** represents a modern solution for patients who have had to endure a standard of care that has remained largely unchanged for centuries.”

The **alfapump** system received U.S. FDA Premarket Approval in December 2024 for the treatment of recurrent or refractory ascites due to liver cirrhosis. It is the first U.S. approved active implantable medical device (Class III) that automatically and continuously removes ascites from the abdomen into the bladder. In August 2025, CMS approved the New Technology Add-on Payment for the **alfapump** when performed in the hospital inpatient setting, effective October 1, 2025. Sequana Medical expects the first U.S. commercial implants to take place early in the fourth quarter of 2025.

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Important Safety Information

Indication for Use: The **alfapump**® System is intended for single patient use only in adult patients with refractory or recurrent ascites due to liver cirrhosis. It is indicated for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder, where it can be eliminated through normal urination.

Contraindications: MRI Safety Information: The **alfapump**® System is MRI unsafe. This diagnostic procedure is contraindicated due to possible movement of the **alfapump**®, damage to the pump circuitry, tissue damage in the vicinity of the **alfapump**® and/or catheter dislocation. Hyperbaric oxygen therapy is contraindicated because the environmental conditions entailed in this therapy are out of the defined range of use for the **alfapump**® System.

Warnings, Risks, and Precautions: The implantation of the **alfapump**® may result in infection that could delay liver transplant or impact transplant listing status. Additional risks associated with implanting the **alfapump**® System including risk of peritoneal cavity infections/peritonitis, Coagulopathy, Small bladder capacity and/or obstructive uropathy. The following procedures or therapies could impact the **alfapump**® System function: Supersonic therapy and high-frequency heat therapy, Transcutaneous Electrical Nerve Stimulation (TENS), Lithotripsy, Defibrillation, Radiation therapy, Electrocautery, or use of other implantable medical devices and wearable devices.

Adverse Events: In addition to procedure related risks the following Adverse Events may occur: pump pocket hematoma, skin erosion, infection, pump migration, catheter clogging or other catheter complications resulting in tissue damage or loss of or change in therapy, genito-urinary complications, reduced kidney function, hepatic encephalopathy, progression of liver disease, and other systemic effects.

Caution: the law restricts the sale by or on the order of a physician. Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Potential Adverse Effects, Warnings and Precautions prior to using this product.

The **alfapump**® System is currently not approved in Canada.

DSR® therapy is still in development and is currently not approved in any country. The safety and effectiveness of DSR® therapy has not been established.

Note: **alfapump**® and DSR® are registered trademarks.

About Sequana Medical

Sequana Medical NV is a pioneer in treating fluid overload, a serious and frequent clinical complication in patients with liver disease, heart failure and cancer. This causes major medical issues including increased mortality, repeated hospitalizations, severe pain, difficulty breathing and restricted mobility. Although diuretics are standard of care, they become ineffective, intolerable or exacerbate the problem in many patients. There are limited effective treatment options, resulting in poor clinical outcomes, high costs and a major impact on their quality of life. Sequana Medical is seeking to provide innovative treatment options for this large and growing “diuretic resistant” patient population. **alfapump**® and DSR® are Sequana

Medical's proprietary platforms that work with the body to treat diuretic-resistant fluid overload, and are intended to deliver major clinical and quality of life benefits for patients, while reducing costs for healthcare systems.

The Company received US FDA approval for the **alfapump** System for the treatment of recurrent or refractory ascites due to liver cirrhosis in December 2024, following the grant of FDA Breakthrough Device Designation in 2019. In Sequana Medical's POSEIDON study, a landmark study across 18 centers in the US and Canada, the pivotal cohort of 40 patients implanted with the **alfapump** showed at 6 and 24 months post-implantation the virtual elimination of therapeutic paracentesis and an improvement in quality of life^{1,2}.

Sequana Medical has commenced US commercialisation through a small specialty salesforce initially targeting US liver transplant centers – 90 of these centers perform more than 90% of US liver transplants annually. CMS has approved the New Technology Add-on Payment for the **alfapump** when performed in the hospital inpatient setting as of October 1, 2025.

Results of the Company's RED DESERT and SAHARA proof-of-concept studies in heart failure published in European Journal of Heart Failure in April 2024 support DSR's mechanism of action as breaking the vicious cycle of cardiorenal syndrome. All three patients from the non-randomized cohort of MOJAVE, a US randomized controlled multi-center Phase 1/2a clinical study, have been successfully treated with DSR, resulting in a dramatic improvement in diuretic response and virtual elimination of loop diuretic requirements.³ The independent Data Safety Monitoring Board approved the start of the randomized MOJAVE cohort of up to a further 30 patients, which is dependent on securing additional financing.

Sequana Medical is listed on the regulated market of Euronext Brussels (Ticker: SEQUA.BR) and headquartered in Ghent, Belgium. For further information, please visit www.sequanamedical.com.

Forward-looking statements

This press release may contain predictions, estimates or other information that might be considered forward-looking statements. Such forward-looking statements are not guarantees of future performance. These forward-looking statements represent the current judgment of Sequana Medical on what the future holds, and are subject to risks and uncertainties that could cause actual results to differ materially. Sequana Medical expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release, except if specifically required to do so by law or regulation. You should not place undue reliance on forward-looking statements, which reflect the opinions of Sequana Medical only as of the date of this press release.

¹ **alfapump** system SSED (summary of safety and effectiveness) PMA 230044

² as defined by subjective physical health (assessed by SF-36 PCS) and ascites symptoms (assessed by Ascites Q)

³ Data reported in press release of [March 25, 2024](#); mean increase of 326% in six-hour urinary sodium excretion at 3 months follow up vs baseline, and 95% reduction of loop diuretics over same period