PRESS RELEASE
REGULATED INFORMATION
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Sequana Medical Announces U.S. Commercial alfapump® Implantations at University of Pennsylvania

- ***First implantation of two alfapump patients on the same day***
- ***Continuing strategy of working with Key Opinion Leaders at top tier centers***
- ***Strong pipeline of additional implanting centers supports commercial momentum***
- ***Ongoing progress in bringing breakthrough treatment option to US patients with recurrent and refractory ascites due to liver cirrhosis***

Ghent, Belgium – [11] December 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 the successful completion of the first commercial implantations of the **alfa**pump® System at the University of Pennsylvania, with two patients implanted on the same day. The **alfa**pump System is the first active implantable medical device approved in the U.S. for the treatment of recurrent or refractory ascites due to liver cirrhosis that automatically and continuously removes ascites fluid from the abdomen into the bladder.

These successful implantations at University of Pennsylvania follow the successful procedure at Mount Sinai Hospital in New York and are further demonstration of the Company's strategy of working with Key Opinion Leaders at top tier centers to establish alfapump as the new standard of care. Sequana Medical continues to make strong progress in the roll-out of this strategy with a growing pipeline of additional centers completing the necessary site approvals for implantation, and keen interest from both clinicians and patients supporting the commercial momentum.

Recurrent or refractory ascites is a severe condition characterized by the accumulation of fluid in the abdomen. The current standard treatment involves therapeutic paracentesis, an invasive and burdensome procedure that drains ascites from the abdomen using a large needle. This procedure often needs to be repeated weekly or monthly, requiring frequent hospital visits and causing significant disruption to patients' daily lives.[1] Sequana Medical estimates there are approximately 70,000 patients in the U.S. with recurrent or refractory ascites, representing a market opportunity in excess of $2 billion for the **alfa**pump, forecast to reach 130,000 patients and over $5 billion by 2035, primarily driven by NASH/MASH and alcoholic liver disease.[2]

Ethan Weinberg MD, Associate Professor of Clinical Medicine at the University of Pennsylvania, commented*: "The **alfa**pump represents a welcomed advancement for our patients suffering from recurrent ascites. With the **alfa**pump system, patients can have ascites drained automatically and continuously avoiding the punctures and the hospital visits. This engineering marvel offers our patients the potential for improved quality of life, allowing them to get back to their daily lives."*

Martijn Blom, Chief Commercial Officer of Sequana Medical, continued: *"Today marks another big step forward in bringing **alfa**pump to the patients who deserve it, with two patients treated on the same day*

*at the University of Pennsylvania. Here is another top-tier US hospital with a strong reputation in hepatology and interventional radiology starting to implant the **alfa**pump in a commercial setting, and we are proud to work alongside them to deliver this breakthrough device to patients that currently undergo repeated needle puncture paracentesis. **alfa**pump is a twenty-first century solution for the large and growing patient population that has clear unmet clinical needs."*

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Important Safety Information

Indication for Use: The **alfa**pump® 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 **alfa**pump® System is MRI unsafe. This diagnostic procedure is contraindicated due to possible movement of the **alfa**pump®, damage to the pump circuitry, tissue damage in the vicinity of the **alfa**pump® 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 **alfa**pump® System.

Warnings, Risks, and Precautions: The implantation of the **alfa**pump® may result in infection that could delay liver transplant or impact transplant listing status. Additional risks associated with implanting the **alfa**pump® System including risk of peritoneal cavity infections/peritonitis, Coagulopathy, Small bladder capacity and/or obstructive uropathy. The following procedures or therapies could impact the **alfa**pump® 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.

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: **alfa**pump® 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. **alfa**pump® 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 **alfa**pump 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 **alfa**pump showed at 6 and 24 months post-implantation the virtual elimination of therapeutic paracentesis and an improvement in quality of life[3, 4].

Sequana Medical is commercializing the **alfa**pump through a specialty commercial team initially targeting US liver transplant centers – 90 of these centers perform more than 90% of US liver transplants annually. In August 2025, CMS announced that it approved the New Technology Add-on Payment for the **alfa**pump 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.[5] 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.

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[1] Wong F, Bendel E, Sniderman K, et al. Improvement in Quality of Life and Decrease in Large-Volume Paracentesis Requirements With the Automated Low-Flow Ascites Pump. *Liver Transpl*. 2020;26(5):651-661. doi:10.1002/lt.25724

[2] Based on US and Canada market assessment conducted by highly experienced international consulting group

[3] ***alfa****pump system SSED (summary of safety and effectiveness) PMA 230044*

[4] *as defined by subjective physical health (assessed by SF-36 PCS) and ascites symptoms (assessed by Ascites Q)*

[5] 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