PRESS RELEASE
NON-REGULATED INFORMATION
31 July 2025, 6:00 pm CET

Use of alfapump® to control ascites enabling elective umbilical hernia repair published in *Hernia*

- **Untreated umbilical hernias occur in 20% of patients with ascites due to liver cirrhosis. Without treatment, there is a significant risk of complications that are life threatening and require emergency surgery**
- **Effective management of ascites is necessary for elective surgical repair in such patients**
- **The team at Mayo Clinic, Arizona present a case report of a patient in the POSEIDON study that underwent a successful robotic hernia repair following control of their ascites with the alfapump**
- **US commercial launch remains on track for this quarter through specialty commercial team focused on liver transplant centers**

Ghent, Belgium – 31 July 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 announces the publication of "Using the **alfa**pump to control ascites enabling elective umbilical hernia repair: A case report" in the prestigious peer-reviewed journal, *Hernia*. The case study presented a patient from the POSEIDON study that received an **alfa**pump for control of his ascites and subsequently underwent a robotic repair of his umbilical hernia. The publication is available online here.

Dr. H.E. Vargas, M.D., Professor of Medicine for the Mayo Clinic College of Medicine (Phoenix, Arizona, US), commented: *"Umbilical hernias are an important problem in patients with recurrent and refractory ascites, with a major impact on their quality of life as well as significant risk of complications if left untreated. Successful hernia repair is a challenge in these patients due to the need to manage the ascites both ahead of surgery and post-repair. In this case study we report on a patient from the POSEIDON from study that received an **alfa**pump, and subsequently achieved successful control of their ascites. As a result of this, the patient was able to undergo a successful robotic repair of their hernia."*

Dr. Gijs Klarenbeek, Chief Medical Officer of Sequana Medical NV continued: *"We are delighted with this thoughtful publication by the team at the Mayo Clinic in Arizona. It is a further demonstration of how the **alfa**pump can benefit this large and growing population of patients with recurrent or refractory ascites due to liver cirrhosis. For too long, they have had to put up with a standard of care that has changed little in over 2,000 years. The **alfa**pump is a 21st century solution recognising that cirrhosis is increasingly a mainstream disease and patients are demanding and deserve better treatment options."*

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About alfapump in recurrent or refractory ascites due to liver cirrhosis & the POSEIDON study
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 over an extended period. The **alfa**pump is approved by the US FDA for the treatment of recurrent or refractory ascites due to liver cirrhosis. It is the first active implantable medical device in the US that automatically and continuously removes ascites from the abdomen into the bladder, where it is naturally eliminated through urination. To date, over 1,000 **alfa**pump systems have been implanted.

The US market of recurrent and refractory ascites due to liver cirrhosis is forecast to grow by an average of 9% per year, from approximately 70,000 patients in 2025 to 130,000 patients by 2032, primarily driven by the increasing prevalence of NASH / MASH[1]. The total market opportunity for **alfa**pump is estimated at over $2 billion in 2025.

The Company is planning to commence US commercialisation in Q3 2025 through its own speciality salesforce targeting US liver transplant centers; 90 centers perform more than 90% of liver transplant procedures in the US.

The FDA's approval of the PMA is based on the successful execution of Sequana Medical's pivotal POSEIDON study, a landmark study across 18 centers in the US and Canada with a total of 69 patients implanted with the **alfa**pump. The primary effectiveness endpoints at six months post-implantation in the Pivotal Cohort[2] exceeded the predefined thresholds with statistical significance, and primary safety endpoint data was in line with expectations[3]. Data at 12 months post-implantation continued to show a strong and durable clinical profile, virtually eliminating the need for therapeutic paracentesis and delivering an improvement in quality of life (as defined by subjective physical health (assessed by SF-36 PCS) and ascites symptoms (assessed by Ascites Q))[4]. At AASLD's The Liver Meeting in November 2024, key POSEIDON investigators reported that the **alfa**pump virtually eliminated the need for large volume paracentesis at 24 months, with overall survival of 62%[5].

Data from the patient preference study and a matched cohort analysis of the NACSELD-III registry with the POSEIDON Pivotal Cohort indicated that US patients have a strong preference for the **alfa**pump vs standard paracentesis procedures and that the safety profile of the **alfa**pump is comparable to standard of care.[6]

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

[1] Based on US market assessment conducted by highly experienced international consulting group
[2] The Pivotal Cohort is used for the primary effectiveness endpoints and consists of 40 patients implanted with the **alfa**pump
[3] Data reported in press release of 25 October 2022
[4] Data reported in press release of 19 October 2023
[5] Based upon the pivotal cohort of the POSEIDON study, data reported in press release of 18 November 2024
[6] Data reported in press release of 19 October 2023; Patient Preference study conducted by RTI Health Solutions, and matched cohort analysis presented by Dr. Bajaj at EASL Congress 2024.

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.

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[7]. 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.

Important Safety Information: For important safety information regarding the **alfa**pump® system, see https://www.sequanamedical.com/wp-content/uploads/ISI.pdf.

The **alfa**pump® 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: **alfa**pump® and DSR® are registered trademarks.

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.

[7] 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