PRESS RELEASE
NON-REGULATED INFORMATION
7 January 2025, 07:00 am CET

sequanamedical

Six Month Data from alfapump® Pivotal POSEIDON Study in Treatment of Recurrent or Refractory Ascites due to Liver Cirrhosis Published in *American Journal of Gastroenterology*

- **alfapump® system is effective in controlling ascites in decompensated cirrhosis with recurrent or refractory ascites by reducing or even eliminating the need for therapeutic paracentesis[1]**
- **Reduction was associated with a significant improvement in quality of life[1,2]**
- **10 additional good health days per month in these patients[1]**
- **Safety events consistent with those observed for this patient population[1]**
- **Overall survival of alfapump patients was higher than reported for standard of care and not worse compared to TIPS[1,3, 4]**
- **US PMA approval[5] received in December 2024 and US commercial launch planned for H2 2025**

Ghent, Belgium – 7 January 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 "The Effects of **alfa**pump on Ascites Control and Quality of Life in Patients with Cirrhosis and Recurrent or Refractory Ascites" in the prestigious peer-reviewed journal, *American Journal of Gastroenterology*. The publication covered the six month data for the forty implanted patients in the pivotal cohort of the POSEIDON study, the multicenter, open-label, single arm study with a within-subject crossover design conducted in patients with cirrhosis and recurrent or refractory ascites. The publication is available online here.

Professor Florence Wong, University of Toronto, Hepatologist at Toronto General Hospital, Ontario, Canada and Principal Investigator for the POSEIDON study, commented: *"Patients with recurrent or refractory ascites have a very poor quality of life and reliance upon large volume paracentesis (LVP) imposes a substantial burden on them, as well as their caregivers and the health care system. The results from the POSEIDON study in this publication have shown that the **alfa**pump system effectively controlled ascites, which improved quality of life[2], with complication rates similar to the expectation in patients with refractory ascites at six months post-implantation[1]. Results from the literature indicate that the overall survival of patients with the **alfa**pump was not worse as compared to TIPS[3,4] and was higher than reported for standard of care (LVP)."*

[1] Data on file; statements from "The Effects of **alfa**pump on Ascites Control and Quality of Life in Patients with Cirrhosis and Recurrent or Refractory Ascites" A*merican Journal of Gastroenterology [January 2025]*
[2] as defined by subjective physical health (assessed by SF-36 PCS) and ascites symptoms (assessed by Ascites Q)
[3] Transjugular intrahepatic portosystemic stent shunt
[4] a) Tan HK, James PD, Wong F. Albumin may prevent the morbidity of paracentesis-induced circulatory dysfunction in cirrhosis and refractory ascites: A pilot study. Dig Dis Sci 2016;61:3084-3092; b) Salerno F, Cammà C, Enea M, Rössle M, Wong F. Transjugular intrahepatic portosystemic shunt for refractory ascites: a meta-analysis of individual patient data. Gastroenterology 2007;133:825-834.
[5] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230044

Dr Gijs Klarenbeek, Chief Medical Officer of Sequana Medical NV, who has led the POSEIDON study for the Company, continued: *"We are delighted with this thoughtful publication of the six month results from our POSEIDON study, and we thank all of the investigators and study teams. In addition to the reduction or virtual elimination of the need for the therapeutic paracentesis[6], we are very pleased with the results highlighting the additional 10 good health days per month, which we believe is of great importance to these patients and their desire to take back control of their lives. This paper combined with the 24 month POSEIDON data presented at the 2024 AASLD meeting by the study investigators presents a comprehensive view of how the **alfa**pump can deliver such important benefits to this large and growing patient population that have been overlooked for far too long[7]. Following the **alfa**pump's US FDA approval[5] in December, we are stepping up our preparations for US commercial launch planned for H2 2025."*

For more information, please contact:
Sequana Medical
Investor relations
E: IR@sequanamedical.com
T: +44 (0) 797 342 9917

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[8]. The total market opportunity for **alfa**pump is estimated at over $2 billion in 2025, including approximately $500 million from the Company's initial priority target market of patients requiring at least 12 paracenteses per year.

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[9] exceeded the predefined thresholds with statistical significance, and primary safety endpoint data was in line with expectations[10]. 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

[6] Based upon 100% median reduction in therapeutic paracentesis in the POSEIDON pivotal cohort
[7] https://www.aasld.org/sites/default/files/2024-10/1_the_liver_meeting_2024_abstracts.pdf
[8] Based on US market assessment conducted by highly experienced international consulting group
[9] The Pivotal Cohort is used for the primary effectiveness endpoints and consists of 40 patients implanted with the **alfa**pump
[10] Data reported in press release of 25 October 2022

defined by subjective physical health (assessed by SF-36 PCS) and ascites symptoms (assessed by Ascites Q))[11]. 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%[12].

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.[13]

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.

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[14]. The independent Data Safety Monitoring Board approved the start of the randomized MOJAVE cohort of up to a further 30 patients, which is planned after **alfa**pump US PMA approval.

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.

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: The **alfa**pump® System is MRI unsafe. Hyperbaric oxygen therapy is contraindicated.

Warnings, Risks, and Precautions: Consider risks associated with implanting the **alfa**pump® System including risk of peritoneal cavity infections, Coagulopathy, Small bladder capacity and/or obstructive uropathy. The

[11] Data reported in press release of 19 October 2023
[12] Based upon the pivotal cohort of the POSEIDON study, data reported in press release of 18 November 2024
[13] 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.
[14] 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

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.

P230044 PMA approval letter on file

U.S. Federal law restricts **alfa**pump System to sale by or on the order of a physician.

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.