PRESS RELEASE

sequanamedical

Abstract on quality of life & safety of alfapump® accepted for presentation at EASL Congress 2024

Comparison of POSEIDON Pivotal Cohort vs. NACSELD-III Supports Strong Commercial Messaging for alfapump

Poster presentation by Dr. Jasmohan S. Bajaj on 7 June 2024

Ghent, Belgium – 10 April 2024 – Sequana Medical NV (Euronext Brussels: SEQUA) (the "**Company**" or "**Sequana Medical**"), a pioneer in the treatment of fluid overload in liver disease, heart failure and cancer, today announces that the abstract including data from i) its North American pivotal POSEIDON study of the **alfa**pump and ii) matched interim analysis of patients from the NACSELD-III[i] registry, in patients with recurrent or refractory ascites due to liver cirrhosis has been selected for a poster presentation at the EASL Congress 2024, Europe's largest event in this domain, taking place in Milan, Italy from 5 to 8 June 2024.

Details Poster Presentation

- Title: **alfa**pump implantation significantly improved quality of life and showed similar safety outcomes compared to a contemporaneously enrolled refractory ascites cohort
- Presenter: Dr. Jasmohan S Bajaj, MD, Professor of Medicine, Division of Gastroenterology, Hepatology, and Nutrition, Virginia Commonwealth University and Richmond VA Medical Center
- Date: 7 June 2024
- Session: Cirrhosis and its complications: Other clinical complications except ACLF and critical illness

The abstract and poster will become available on the website of EASL prior to the start of the conference. Sequana Medical management will attend the EASL Congress and is available to meet.

For more information, please contact:

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About alfapump in recurrent or refractory ascites due to liver cirrhosis

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. If approved by the FDA, the **alfa**pump could become 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.

The PMA application submitted to the US FDA was 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[ii] exceeded the predefined thresholds with statistical significance, and primary safety endpoint data was in line with expectations[iii]. Data at 12 months post-implantation continued to show a strong and durable clinical profile, virtually eliminating the need for therapeutic paracentesis and delivering a clinically meaningful improvement in patients' quality of life[iv].

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.

The North American market of recurrent and refractory ascites due to liver cirrhosis is forecast to grow on average 9% per year, from approximately 78,000 patients in 2025 reaching 147,000 patients by 2032, primarily driven by the increasing prevalence of NASH[v]. The total market opportunity for **alfa**pump is estimated at $2.4 billion in 2025, including approximately $600 million from the Company's initial priority market targeting patients requiring at least 12 paracentes per year. To date, over 1,000 **alfa**pump systems have been implanted.

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, untolerable 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, delivering major clinical and quality of life benefits for patients and reducing costs for healthcare systems.

The Company's Premarket Approval (PMA) application for the **alfa**pump was submitted to the US FDA in December 2023 and accepted for substantive review in January 2024, having reported positive primary and secondary endpoint data from the North American pivotal POSEIDON study in recurrent or refractory ascites due to liver cirrhosis.

Results of the Company's RED DESERT and SAHARA proof-of-concept studies in heart failure 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. 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.

Important Regulatory Disclaimers

*The **alfa**pump® system is currently not approved in the United States or Canada. In the United States and Canada, the **alfa**pump system is currently under clinical investigation (POSEIDON Trial) and is being studied in adult patients with refractory or recurrent ascites due to liver cirrhosis. DSR® therapy is still in development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. There is no link between DSR therapy and ongoing investigations with the **alfa**pump system in Europe, the United States or Canada.*

*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.

[i] NACSELD is the North American Consortium for the Study of End Stage Liver Disease. A matched cohort analysis was conducted by an independent group comparing outcomes of decompensated cirrhosis patients from the NACSELD-III registry to those from the POSEIDON study; see press release of 19 October 2023
[ii] The Pivotal Cohort is used for the primary effectiveness endpoints and consists of 40 patients implanted with the **alfa**pump
[iii] Data reported in press release of 25 October 2022
[iv] Data reported in press release of 19 October 2023
[v] Based on US and Canada market assessment conducted by highly experienced international consulting group