

Additional data from North American pivotal alfapump® study (POSEIDON) will be presented at EASL Congress 2023

- *Poster presentation at EASL by Dr. Florence Wong on 21 June 2023; selected for additional poster presentation on 23 June 2023*
- *Conference call with [live webcast](#) by Sequana Medical on 21 June 2023 at 03:00 pm CEST / 09:00 am EST*

Ghent, Belgium – 19 June 2023 – 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 data from POSEIDON, its North American pivotal study of the alfapump will be presented during two poster sessions at the EASL Congress 2023, taking place in Vienna, Austria from 21 to 24 June 2023.

The poster will include primary and secondary endpoint data from Pivotal Cohort patients in the POSEIDON study¹, including reduction in paracentesis requirement, safety, quality of life and survival.

Details oral poster presentations at EASL 2023

- **Title:** "The effects of alfapump on ascites control and quality of life in patients with cirrhosis and recurrent or refractory ascites: pivotal trial results"
- **Presenter:** Dr. Florence Wong, MD, FAASLD, University of Toronto
- **Track:** Cirrhosis & complications
- **Timing:** Wednesday, 21 June 2023; highlights on Friday, 23 June 2023 between 12:45 – 12:55 CEST

Sequana Medical management will attend the EASL Congress and is available to meet.

Conference Call and Webcast

Sequana Medical management will host a conference call with a live webcast presentation on Wednesday, 21 June 2023 at 03:00 pm CEST / 09:00 am EST.

- Registration webcast: please click [here](#)
- Registration conference call (only if you wish to participate in the Q&A): please click [here](#). Once registered, you will receive dial-in numbers and a confirmation code.

The webcast and conference call will be conducted in English and a replay will be available on Sequana Medical's [website](#) shortly after.

¹ Positive primary endpoint data reported in [press release](#) on 25 October 2022

For more information, please contact:**Sequana Medical**

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About the POSEIDON study

POSEIDON is a single-arm, open-label, within-subject crossover study of the **alfapump** in patients with recurrent and refractory ascites due to liver cirrhosis in approximately 20 centres across the US and Canada. The study consisted of a Pivotal Cohort for primary endpoint analysis and an additional Roll-In Cohort for new centers to become familiarized with the implantation procedure before they enrolled patients in the Pivotal Cohort. Pivotal Cohort patients entered into a three-month pre-implant observation period in which they received standard of care therapy (consisting of therapeutic paracentesis (TP)) before the **alfapump** was implanted.

Pivotal Cohort patients met all pre-specified primary effectiveness endpoints with statistical significance at six months post-implantation, including i) 100% median per-patient reduction in TP post- vs pre-implantation ($p < 0.001$), vs hypothesis of at least a 50% reduction and ii) 77% of patients with at least 50% reduction in number of TP post- vs pre-implantation ($p < 0.001$), vs hypothesis of at least 50% of patients. Primary safety endpoint data, including the rate of **alfapump**-related re-interventions adjudicated by the Clinical Events Committee, were in line with expectations with no unanticipated adverse device effects.

Patients are followed for up to two years post-implant for analysis of secondary outcome measurements including safety (device and/or procedure-related adverse events), quality of life (assessed by general SF36 as well as disease-specific Ascites Q questionnaires), nutritional status, health economics and overall survival.

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. These patients can have up to 15 liters of extra fluid in their bodies, causing major medical issues including increased mortality, repeated hospitalizations, severe pain, difficulty breathing and restricted mobility that severely impacts daily life. Although diuretics are standard of care, the problem is that in many patients they are no longer effective and / or tolerable. There are limited effective treatment options for these patients, 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, delivering major clinical and quality of life benefits for patients and reducing costs for healthcare systems. The Company has reported positive primary endpoint data from the North American pivotal POSEIDON trial of the **alfapump** in recurrent or refractory ascites due to liver cirrhosis, enabling the filing of a Pre-Market Approval (PMA) application with the FDA, planned for H2 2023. Having delivered clinical proof-of-concept for **DSR** as a disease-modifying drug program for the treatment of heart failure, the Company will commence MOJAVE, a US randomized controlled multi-center Phase 1/2a clinical trial of **DSR 2.0**, with initial data expected in Q4 2023.

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

Important Regulatory Disclaimers

*The **alfapump**[®] system is currently not approved in the United States or Canada. In the United States and Canada, the **alfapump** system is currently under clinical investigation (POSEIDON Trial) and is being studied in adult patients with refractory or recurrent ascites due to 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 **alfapump** system in Europe, the United States or Canada.*

*Note: **alfapump**[®] 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.