# Data from Roll-In Cohort of North American pivotal alfapump® study (POSEIDON) selected for poster presentation at AASLD The Liver Meeting®

***Presentation by Dr. Florence Wong on Sunday November 6th in Washington, DC:***
***"An Automatic Low Flow Ascites Pump Improves Ascites Control and Quality of Life In Patients with Cirrhosis and Recurrent Ascites"***

**Ghent, Belgium – 21 October 2022 – 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 that data from the Roll-In Cohort of POSEIDON[1], its North American pivotal **alfa**pump study, have been selected for a poster presentation at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting, taking place in Washington, DC from 4 to 8 November 2022.

The poster, titled "An Automatic Low Flow Ascites Pump Improves Ascites Control and Quality of Life In Patients with Cirrhosis and Recurrent Ascites", will be presented by Dr. Florence Wong, MD, FAASLD, University of Toronto on Sunday, November 6th between 1:00-2:00pm EST. The abstract will become available on the AASLD website prior to the start of The Liver Meeting.

A full list of presentations can be found here: https://www.aasld.org/the-liver-meeting

Sequana Medical management will attend The Liver Meeting and is available to meet.

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[1] Results from a secondary interim analysis from the Roll-In Cohort of the POSEIDON study were announced in a press release on 1 July 2021.

**About the POSEIDON study**

POSEIDON is a single-arm, open-label and within subject cross-over study of the **alfa**pump in patients with recurrent or refractory ascites due to liver cirrhosis and is being conducted in approximately 20 centres across the US and Canada. All patients have been enrolled in the study and implanted with the **alfa**pump. Patients enrolled in the Pivotal Cohort entered into a three-month pre-implant observation period before they are implanted with the **alfa**pump and will be used for primary endpoint analysis. The study allowed to enrol additional patients in a Roll-In Cohort to ensure new centres were experienced with the **alfa**pump implantation prior to enrolling patients in the Pivotal Cohort.

The primary effectiveness outcomes of the study include the proportion of patients with a 50% reduction in the average frequency of therapeutic paracentesis per month in the post-implant observation period (month four to month six post-implantation) as compared to the pre-implant observation period. The primary safety endpoint is the rate of **alfa**pump-related re-interventions adjudicated by the Clinical Events Committee. Patients will be 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. For more information about the study, please visit clinicaltrials.gov (NCT03973866).

**About fluid overload in liver cirrhosis (AKA ascites)**

Fluid accumulation in the abdomen is a significant and common complication of liver cirrhosis. Approximately 10% of these patients do not respond to diuretic drugs and most require recurrent external drainage (AKA paracentesis), an invasive and painful procedure that only provides temporary benefit, require frequent hospitalizations and severely impacts their quality of life.

**About Sequana Medical**

Sequana Medical NV is a pioneer in treating drug-resistant fluid overload, a serious and frequent clinical complication in patients with liver disease, heart failure and cancer. Fluid overload is a well-recognized problem in these growing diseases, causing severe problems for the large number of patients for whom current medicines are no longer effective. 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, difficult breathing and restricted mobility that severely impacts daily life.

**alfa**pump and DSR are Sequana Medical's proprietary approaches that work with the body to remove this excess fluid, delivering major clinical and quality of life benefits for patients and reducing costs for healthcare systems. 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 **alfa**pump® system is not currently approved in the United States or Canada. In the United States and Canada, the **alfa**pump® system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the*

*POSEIDON clinical study see www.poseidonstudy.com. 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. DSR therapy is not currently approved for clinical research in the United States or Canada. 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® is a registered trademark. DSR® is a registered trademark in the Benelux, China, the EU, United Kingdom, and Hong Kong.*

***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.*