Sequana Medical announces the completion of patient enrolment in POSEIDON, the North American pivotal alfapump® study

- **Positive interim analysis reported in July 2021**
- **Reporting of primary endpoint planned for Q4 2022**

Ghent, Belgium – 6 December 2021 – Sequana Medical NV (Euronext Brussels: SEQUA, the "Company" or "Sequana Medical"), an innovator in the treatment of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure, today announces the completion of patient enrolment in POSEIDON, the North American pivotal study to support regulatory approval of the **alfa**pump system in the U.S. and Canada, for the treatment of recurrent or refractory ascites due to liver cirrhosis.

70 patients have been enrolled in the Pivotal Cohort, with the objective to implant up to 50 patients with the **alfa**pump by the end of Q1 2022 and to evaluate up to 40 patients for the primary endpoint six months post-implantation. Reporting of the primary endpoint is planned for Q4 2022. A further 40 patients were enrolled in the Roll-In Cohort and implanted with the **alfa**pump.

Ian Crosbie, Chief Executive Officer of Sequana Medical, commented: "Completing the patient enrolment in our POSEIDON study is an important step in bringing the **alfa**pump closer to market approval in the U.S. and Canada. We are grateful to the patients and the clinicians involved in this study. They are allowing us to evaluate the **alfa**pump as a potential treatment option for recurrent or refractory ascites due to liver cirrhosis, which is a growing healthcare problem due to the dramatic rise in non-alcoholic steatohepatitis (NASH). The positive interim results reported in July 2021 demonstrated that the **alfa**pump brings great benefits, including a reduction of more than 90% in the rate of therapeutic paracentesis and clinically important improvements in quality of life. We look forward to reporting the primary endpoint data in Q4 2022, followed by Premarket Approval (PMA) submission to the FDA in mid-2023."

Summary of the 2nd Interim Analysis reported in July 2021

In July 2021, the Company reported the second interim analysis on 26 patients from the Roll-In Cohort (underlying etiology: 50% alcohol, 23% non-alcoholic steatohepatitis (NASH), 4% NASH-alcohol, 4% hepatitis and 19% other/mixed etiology) implanted with the **alfa**pump. The results of this analysis substantially exceeded the primary endpoints as defined for the Pivotal Cohort in the study[1] and demonstrated (i) over 90% reduction in mean frequency of therapeutic paracentesis (TP) versus baseline, (ii) all patients having at least a 50% reduction in mean frequency of TP per month versus baseline, (iii) clinically important improvement in quality of life maintained even up to 12 months post-implantation and (iv) safety profile in line with expectations.

[1] Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis

2022 Financial Calendar

31 March 2022	Publication of Full Year Results 2021
27 April 2022	Online Publication of Annual Report 2021
27 May 2022	Annual General Meeting 2022
8 September 2022	Publication of Half Year results 2022

For more information, please contact:

Sequana Medical
Lies Vanneste
Director Investor Relations
Tel: +32 498 05 35 79
Email: IR@sequanamedical.com

LifeSci Advisors
Guillaume van Renterghem
Tel: +41 76 735 01 31
Email: gvanrenterghem@lifesciadvisors.com

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 U.S. and Canada. Patients enrolled in the Pivotal Cohort enter into the pre-implant observation period, allowing for up to 50 patients to be implanted with the **alfa**pump for primary endpoint analysis. The study allows for additional patients to be enrolled in a Roll-In Cohort, to ensure centres are experienced with the **alfa**pump implantation prior to enrolment of patients in the Pivotal Cohort. Pivotal Cohort patients enter a three-month pre-implant observation period during which they receive standard of care therapy (consisting of therapeutic paracentesis) before the **alfa**pump is implanted. Patients from the Roll-In Cohort are immediately implanted with the **alfa**pump.

The primary effectiveness outcomes of the study include the proportion of patients with a 50% reduction in the overall 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 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 Sequana Medical

Sequana Medical is a commercial stage medical device company utilizing its proprietary **alfa**pump® and DSR® (Direct Sodium Removal) technologies to develop innovative treatments for fluid overload in liver disease, malignant ascites and heart failure where diuretics are no longer effective. Fluid overload is a frequent complication of many large diseases - including advanced liver disease driven by NASH (non-alcoholic steatohepatitis)-related cirrhosis and heart failure - with diuretic resistance being widespread. The U.S. market for the **alfa**pump resulting from NASH-related cirrhosis is forecast to exceed €3 billion annually within the next 10-20 years. The heart failure market for DSR and the **alfa**pump DSR® is estimated to be over €5 billion annually in the U.S. and EU5 by 2026.

The **alfa**pump is Sequana Medical's unique, fully implanted wireless device that automatically pumps fluid from the abdominal cavity into the bladder, where it is naturally eliminated through urination. DSR is Sequana Medical's proprietary approach to managing sodium and fluid overload through use of a sodium-free infusate administered into the abdominal cavity.

In the U.S., the Company's key growth market, the **alfa**pump has been granted breakthrough device designation by the FDA for recurrent or refractory ascites due to liver cirrhosis. Interim data from the ongoing North American pivotal study (POSEIDON) showed positive outcomes against all primary endpoints and a rapid and persistent clinically important improvement in quality of life. Completion of patient enrolment has been announced and the primary endpoint reporting is planned for Q4 2022. This study is intended to support a future marketing application of the **alfa**pump in the U.S. and Canada. In Europe, the **alfa**pump is CE-marked for the management of refractory ascites due to liver cirrhosis and malignant ascites and is included in key clinical practice guidelines. Over 900 **alfa**pump systems have been implanted to date.

Sequana Medical has combined its proven **alfa**pump and proprietary DSR therapy, and is developing the **alfa**pump DSR, a breakthrough approach to fluid overload due to heart failure. RED DESERT demonstrated that repeated DSR therapy in diuretic-resistant heart failure patients is able to not only manage the fluid and sodium balance of these patients but also restore their diuretic response and improve their cardio-renal status. The SAHARA DESERT study of **alfa**pump DSR in decompensated heart failure patients is ongoing.

Sequana Medical is 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. The 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. The DSR® therapy is not currently approved for clinical research in the United States or Canada. There is no link between the 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® and **alfa**pump DSR® are registered trademarks 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.