PRESS RELEASE
REGULATED INFORMATION - INSIDE INFORMATION
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Sequana Medical announces FDA approval to expand patient enrolment in North American pivotal alfapump® study (POSEIDON)

- **Completion of patient enrolment expected before end of year**
- **Primary endpoint read-out due in Q4 2022**
- **59 patients already recruited in the Pivotal Cohort**

Ghent, Belgium – 4 October 2021 – Sequana Medical NV (Euronext Brussels: SEQUA, the "Company"), an innovator in the treatment of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure, today announces that is has received approval from the U.S. Food and Drug Administration (FDA) to expand patient enrolment to 70 (an increase of 10) in the Pivotal Cohort of POSEIDON, the North American pivotal study of the **alfa**pump for the treatment of recurrent or refractory ascites due to liver cirrhosis. This patient enrolment expansion was requested by Sequana Medical to compensate for the higher rate of attrition between study enrolment and **alfa**pump implantation in the Pivotal Cohort, with the objective to reach 50 patients implanted with the **alfa**pump.

To date, 59 patients have been enrolled in the Pivotal Cohort. The Company expects completion of patient enrolment by end of year with primary endpoint read-out in Q4 2022, on time for FDA regulatory submission mid-2023.

Ian Crosbie, Chief Executive Officer at Sequana Medical, commented: "We welcome the approval from the FDA to expand patient recruitment in POSEIDON and look forward to announcing completion of enrolment. We will now resume our efforts to enrol these additional patients, having had to pause these pending this approval. The interim POSEIDON data has produced strong results which indicate the potential of the **alfa**pump to provide an efficacious treatment that can dramatically improve the quality of life for patients with recurrent or refractory liver ascites. We will continue to work diligently to bring the **alfa**pump one step closer to the growing number of patients that need a 21st century treatment for this terrible disease."

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About the POSEIDON study

POSEIDON is a single-arm, open-label, 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 are being enrolled in the Pivotal Cohort, entering 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 up to 35 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 into a three month pre-implant observation period in 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.

A detailed review of study enrolment in H1 2021, including an analysis of attrition between study enrolment and planned **alfa**pump implantation, identified a higher rate of attrition than forecast when the study was planned. The cause of this included a number of patients whose **alfa**pump implantation was delayed for COVID-related matters and subsequently failed to meet re-evaluation of study inclusion / exclusion criteria prior to implantation, likely due to disease progression. The review concluded that approximately 10 additional patients would need to be enrolled in the Pivotal Cohort in order to implant up to 50 patients with the **alfa**pump following the three-month observation period, leading the Company to submit a protocol amendment to the FDA to extend patient enrolment.

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 after 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), patients' nutritional status, health economics and overall survival. For more information about the study, please visit clinicaltrials.gov (NCT03973866).

In July 2021, the Company reported the second positive interim analysis of the POSEIDON study. Data from 26 patients in the Roll-In Cohort reconfirmed positive outcomes against all primary endpoints[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

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 a 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 of the study and a rapid and persistent clinically important improvement in quality of life. 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 850 **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, the repeated dose **alfa**pump DSR study in diuretic-resistant heart failure patients has demonstrated that repeated DSR therapy is able to both manage the fluid and sodium balance of these patients as well as 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.