PRESS RELEASE
REGULATED INFORMATION – INSIDE INFORMATION
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Sequana Medical announces positive interim data from North American pivotal alfapump® study (POSEIDON)

- **Results from first 13 patients in Roll-In Cohort showed over 90% reduction in mean frequency of therapeutic paracentesis versus baseline**
- **Indication of rapid and persistent clinically relevant improvement in patients' quality of life**
- **Safety profile in line with expectations**
- **Interim data of the full Roll-In Cohort expected in H1 2021**

Conference call with live webcast presentation today at 02:00 pm CET / 08:00 am EDT

Ghent, BELGIUM – 19 November 2020 – Sequana Medical NV (Euronext Brussels: SEQUA), an innovator in the management of fluid overload in liver disease, malignant ascites and heart failure, today announces positive interim results from the first 13 patients in the Roll-In Cohort of the North American pivotal POSEIDON study of the **alfa**pump for the treatment of recurrent or refractory ascites due to liver cirrhosis. These interim data show positive outcomes against all primary endpoints of the study[1], as well as indications of clinically relevant improvements in quality of life measures.

Professor Florence Wong, University of Toronto, Hepatologist at Toronto General Hospital, Ontario, Canada and Principal Investigator for the POSEIDON study, commented: "I am delighted to see the first, positive, results of these roll-in patients. The dramatic reduction in the need for therapeutic paracentesis and improvement in quality of life is consistent with my long experience with the **alfa**pump. The adverse events were as expected in this population of patients and easily controlled with the standard of care treatments. So if the results are replicated in all study patients, it would be an important improvement in the care for this poorly served patient population."

POSEIDON is a single arm, open-label, within subject crossover study of the **alfa**pump in patients with recurrent or refractory ascites due to liver cirrhosis in the U.S. and Canada. The study includes a "Pivotal Cohort" with up to 50 patients implanted with the **alfa**pump for primary endpoint analysis and an additional "Roll-In Cohort" with up to 30 patients to ensure new centres are familiarised with the **alfa**pump system before they enrol patients in the Pivotal Cohort.

The study is designed to demonstrate in Pivotal Cohort patients 1) a 50% reduction in average monthly frequency of therapeutic paracentesis (TP) post-**alfa**pump implant versus pre-implant and that 2) at least 50% of patients will achieve a 50% reduction in the requirement for TP post-implant versus pre-implant. Paracentesis is the mainstay in chronic clinical management of refractory ascites but it is an invasive procedure, requiring frequent hospitalisations, severely impacting patients' quality of life and provides only temporary benefit.

In this interim analysis, 13 patients from the Roll-In Cohort (underlying etiology: 61% alcohol, 23% non-alcoholic steatohepatitis (NASH), 8% hepatitis C and 8% mixed etiology) were implanted with the **alfa**pump. Before enrolment, these patients required on average 3.4 TP per month. The mean reduction in the frequency of TP post-implant versus pre-implant was over 90%, with all patients having at least a 50% reduction in the average frequency of TP per month[1].

[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

Patient's quality of life was assessed via established health-survey questionnaires. Results from SF36 (a general health quality survey) indicated clinically relevant improvements in the physical component score and improvement was seen in all SF36 subscales. Ascites Q, a questionnaire developed for patients with ascites also indicated clinically relevant improvement in patient's quality of life and the improvement was seen in all subdomains of the survey. In both cases, the improvement was seen rapidly (within a month of implantation) and was persistent (6 months after implantation).

Based on these interim data, the safety profile of the **alfa**pump is consistent with previously reported data. The adjudication process by the Clinical Events Committee (CEC) for two **alfa**pump explants in respect of the primary safety outcome is still ongoing.

Ian Crosbie, Chief Executive Officer at Sequana Medical, added: "The substantial reduction in the need for therapeutic paracentesis, good safety profile and clinically relevant improvement in quality of life reported in this study so far is very encouraging. These data further validate the potential of **alfa**pump as a much needed treatment option in this underserved patient population and is an important milestone towards achieving a future marketing application in the U.S. and Canada. The increasing prevalence of NASH-related cirrhosis in this market and the limitations of the current standard of care has been recognized in our FDA Breakthrough Device Designation for **alfa**pump, which will allow us to bring this innovative technology to patients in need as quickly as possible."

Interim data of the full Roll-In Cohort are expected in H1 2021 and primary endpoint read-out of the Pivotal Cohort is expected in Q1 2022. The POSEIDON study is intended to support a future marketing application of the **alfa**pump in the U.S. and Canada, with an FDA submission expected in mid-2022.

Conference Call and Webcast

Sequana Medical will host a conference call with live webcast presentation today at 02:00 pm CET / 08:00 am EDT.

- 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.

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About the pivotal POSEIDON study

This is a single-arm, open-label, within subject crossover study of the **alfa**pump in patients with recurrent or refractory ascites due to liver cirrhosis in approximately 20 centres across the U.S. and Canada. Up to 60

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 30 patients to be enrolled in a Roll-In Cohort, to ensure centres are experienced with the **alfa**pump prior to enrolment of patients in the Pivotal Cohort.

Pivotal Cohort patients will enter into a three month pre-implant observation period in which they will receive standard of care therapy (consisting of therapeutic paracentesis) before the **alfa**pump is implanted. Patients from the Roll-In cohort will upon implementation of the inclusion/exclusion criteria, immediately be 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 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).

About recurrent and refractory ascites

Ascites is a condition where excess fluid builds up in your abdomen. Ascitic fluid is a protein-containing fluid that leaks from the liver as a result of advanced liver cirrhosis. Patients may accumulate as much as 10 to 15 litres of ascitic fluid within the abdomen every 15 days. Patients suffering from recurrent or refractory ascites have limited treatment options and often have severely impacted quality of life due to the severe swelling of the abdomen, resulting in pain, difficulty breathing, moving, sleeping and eating, the development of various hernias and the risk for developing renal dysfunction. The number of patients with refractory liver ascites is expected to increase dramatically due to the growing prevalence of NASH (Non-alcoholic Steatohepatitis)–related cirrhosis.

Sequana Medical's **alfa**pump is a fully-implanted, programmable, wireless, CE-marked device that automatically pumps ascites from the peritoneal cavity into the bladder, where the body eliminates the ascites naturally through urination. The potential of the **alfa**pump to address the unmet medical need in patients with recurrent or refractory ascites has been demonstrated in multiple clinical studies showing a significant reduction in the need for large volume paracentesis and a significant improvement in patients' quality of life.

About Sequana Medical

Sequana Medical is a commercial stage medical device company developing the **alfa**pump platform for the management of fluid overload in liver disease, malignant ascites and heart failure where diuretics are no longer effective. Fluid overload is a fast growing complication of advanced liver disease driven by NASH (non-alcoholic steatohepatitis) related cirrhosis and a common complication in heart failure. 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 the **alfa**pump DSR (Direct Sodium Removal) is estimated to be over €5 billion annually in the U.S. and EU5 by 2026. Both indications leverage Sequana Medical's **alfa**pump, a unique, fully implanted wireless device that automatically pumps fluid from the abdomen into the bladder, where it is naturally eliminated through urination.

In the U.S., the company's key growth market, the **alfa**pump has been granted breakthrough device designation by the FDA. The North American pivotal study (POSEIDON) in recurrent or refractory ascites due to liver cirrhosis is currently underway, and 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 800 **alfa**pump

systems have been implanted to date. Building on its proven **alfa**pump platform, Sequana Medical is developing the **alfa**pump DSR, a breakthrough, proprietary approach to fluid overload due to heart failure. Clinical proof-of-concept was achieved in a first-in-human single dose DSR study and further supported by strong interim safety and efficacy results from the ongoing repeated dose **alfa**pump DSR study (RED DESERT) in heart failure patients.

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.*

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.