PRESS RELEASE

Sequana Medical announces first patient enrolled in North American alfapump® pivotal study (POSEIDON)

- **Study aims to support the approval of the alfa**pump **in U.S. and Canada**
- **Results anticipated by mid-2021**
- **U.S. launch of the alfa**pump **planned for H1 2022**

Ghent, BELGIUM – 25 September 2019 – Sequana Medical NV (Euronext Brussels: SEQUA), innovators in the management of fluid overload in liver disease, malignant ascites and heart failure, today announces that the first patient has been enrolled in the North American pivotal study (POSEIDON) of the **alfa**pump for the treatment of recurrent and refractory ascites due to liver cirrhosis. The POSEIDON study intends to support marketing approval and reimbursement of the **alfa**pump in the U.S. and Canada.

The POSEIDON study is a single-arm, open-label study and is expected to include up to 50 patients to be implanted with the **alfa**pump in approximately 15 centres across the U.S. and Canada for primary endpoint analysis. The primary effectiveness outcome of the study will include the proportion of patients with a 50% reduction in overall average frequency of paracentesis per month post-implantation versus pre-implantation. This endpoint will be evaluated at nine months after enrolment. Patients will be followed for up to two years after implantation for analysis of secondary outcome measurements.

Top-line results from the study are anticipated in mid-2021 and, taking into account the Breakthrough Device Designation of the **alfa**pump granted by the U.S. FDA in January of this year, the Company expects to launch the **alfa**pump in the U.S. in the first half of 2022.

Professor Florence Wong at the University of Toronto, Hepatologist at Toronto General Hospital, Ontario, Canada and Principal Investigator in the POSEIDON study, commented: "The medical community in North America is becoming increasingly aware of other treatment options for patients with cirrhosis complicated by recurrent or refractory ascites, rather than accepting large volume paracentesis as the only treatment option. The **alfa**pump has a proven track record in Europe, where it is already being used commercially, and we believe this technology has the potential to address this difficult-to-treat condition in these patients and significantly improve their quality of life."

Ian Crosbie, Chief Executive Officer at Sequana Medical, added: "The start of the POSEIDON study is another important milestone for Sequana Medical and the next step in bringing the **alfa**pump as a treatment option to patients in North America. We believe there is significant growth potential in this growing and dynamic market where we anticipate the **alfa**pump will have a stronger competitive position due to the increasing prevalence of NASH-related cirrhosis and the inconveniences posed by the current standard of care. We look forward to reporting further progress of the study and expect patient recruitment to be completed by mid-2020 with top-line results anticipated by mid-2021."

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 centres across the U.S. and Canada. Up to 60 patients will be enrolled in the study, 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 also allows for up to 30 patients to be enrolled in a training cohort, to ensure centres are experienced with the **alfa**pump prior to enrolment in the pivotal study cohort.

Pivotal cohort patients will enter into a 3-month pre-implant observation period in which they will receive standard of care therapy (consisting of paracentesis) before the **alfa**pump is implanted. 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 SF-36 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 the alfapump **in recurrent and refractory ascites due to liver cirrhosis**

Ascites, a common complication of liver cirrhosis, is the accumulation of excess fluid in the abdomen. 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 and refractory ascites has been demonstrated in multiple clinical studies showing a significant reduction in the need for large volume paracentesis, where at least 5 litres of fluid is removed (i.e., the current standard of care), and a significant improvement in patients' quality of life.

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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. 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 within the next 10-20 years. The heart failure market for the **alfa**pump DSR (Direct Sodium Removal) is estimated to be over €5 billon in 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 in recurrent and refractory ascites due to liver cirrhosis started in H2 2019 and a commercial launch in the U.S. is planned for H1 2022. 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 700 **alfa**pump systems have been implanted to date.

Building on its proven **alfa**pump platform, Sequana Medical is developing **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 a repeated dose **alfa**pump DSR study in heart failure patients is planned to start in H2 2019, with results expected in H1 2020.

Sequana Medical is headquartered in Ghent, Belgium. For further information, please visit www.sequanamedical.com.

Important Regulatory Disclaimers

*The **alfa**pump has not yet received regulatory approval in the U.S. and Canada. Any statement in this press release about safety and efficacy of the **alfa**pump does not apply to the U.S. and Canada because the device is currently undergoing clinical investigation in these territories.*

*DSR therapy is still in development and it should be noted that any statements in this press release regarding safety and efficacy arise from pre-clinical studies and ongoing clinical investigations which have yet to be completed. There is no link between DSR therapy and ongoing investigations with the **alfa**pump system in Europe, the U.S. and 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.