# Sequana Medical announces unconditional IDE approval from U.S. FDA to start alfapump® pivotal study (POSEIDON)

- **alfa**pump **pivotal study for treatment of recurrent or refractory ascites due to liver cirrhosis**
- **Optimised clinical trial design of up to 50 patients implanted with alfa**pump **in study cohort and shorter follow-up time for primary endpoint analysis**
- **Planned U.S. launch of alfa**pump **moved forward to H1 2022**
- **Proposed rule of Centers for Medicare and Medicaid Services (CMS) on payment system for breakthrough devices is a positive development for the alfa**pump

***Sequana Medical management to host conference call and webcast today at 16:00 CEST / 10:00 ET***

**Ghent, BELGIUM – 4 June 2019 – Sequana Medical NV (Euronext Brussels: SEQUA)**, a commercial stage medical device company focused on the development of innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders, today announces that the U.S. Food and Drug Administration (FDA) has unconditionally approved its Investigational Device Exemption (IDE) application for POSEIDON, the **alfa**pump pivotal study in patients with recurrent or refractory ascites due to liver cirrhosis. The study is intended to support approval and reimbursement of the **alfa**pump in the U.S. & Canada.

"We are delighted with the IDE approval and optimised clinical trial design for POSEIDON and are grateful for the close collaboration with the FDA. As a result, and together with the Breakthrough Device Designation granted in January this year, we have brought forward our plans for U.S. launch of the **alfa**pump to H1 2022", **said Ian Crosbie, CEO of Sequana Medical**. "This is good news for patients as the growing prevalence of cirrhosis due to Non-Alcoholic Steatohepatitis (NASH) makes the need for a modern and convenient ascites treatment all the more important. We are also encouraged by the recent announcement from CMS in respect of proposed changes to the new technology add-on payment (NTAP) pathway for breakthrough devices, which we believe is a very promising development for the **alfa**pump."

"Thanks to the positive interactive review process, we received an unconditional IDE approval in just 30 days", **said Gijs Klarenbeek, CMO of Sequana Medical**. "The FDA has provided us with invaluable advice on the design of the POSEIDON study. The final study design allows for a reduced number of study patients to be enrolled and a shorter follow-up time for primary endpoint analysis. We look forward to a continued collaboration with the FDA and are excited to start POSEIDON together with the investigators participating in this study."

**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. Sixty patients will be enrolled in the study cohort to enter 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 a further 30 patients to be enrolled in a training cohort, to ensure centres are experienced with the **alfa**pump before the study cohort is enrolled. An application for Investigational Testing Authorisation (ITA) has been submitted to Health Canada as well.

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. Eligible patients will be implanted with the **alfa**pump and monitored during a 3-month stabilisation period to adjust the settings of the **alfa**pump as

per patients' needs. After this period of stabilisation, a 3-month post-implant observation period will begin. 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 three to month six after implantation) as compared to the pre-implant observation period and the per-patient ratio of post-implant to pre-implant with respect to average monthly number of therapeutic paracentesis. The primary safety endpoint is the rate of **alfa**pump related re-interventions adjudicated by the Clinical Events Committee. Patients will be followed up 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.

**About the alfa**pump **in recurrent or refractory ascites due to liver cirrhosis**

Ascites, a key complication of liver cirrhosis, is the accumulation of ascitic 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, severe nausea and constipation. Existing treatment options carry the risk of significant or life-threatening side effects, provide only short-term symptomatic relief or have very limited availability. The number of patients with refractory liver ascites is forecast to increase dramatically due to the growing prevalence of NASH (Non-alcoholic Steatohepatitis).

Sequana Medical's **alfa**pump is a fully-implanted, programmable, wireless, CE-marked system 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, which is 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.

A feasibility study in North America in patients with refractory or recurrent ascites has been completed and results were presented at the AASLD (American Association for the Study of Liver Diseases) annual meetings in October 2017 and November 2018.

**Conference Call and Webcast**

Sequana Medical management will host a conference call with a live webcast presentation today at 16:00 CEST / 10:00 ET. The webcast can be accessed here. To participate in the Q&A, please dial one of the numbers below, using confirmation code 9932969. The webcast and conference call will be conducted in English and a replay will be available on the Company's website shortly thereafter.

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**About Sequana Medical**

Sequana Medical is a commercial stage medical device company focused on the development of innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders.

Sequana Medical's technology is based on its proprietary **alfa**pump platform, which is applicable across multiple life-threatening disorders. The **alfa**pump is being commercialised in Europe for the management of refractory ascites (chronic fluid build-up in the abdomen) due to liver cirrhosis and malignant ascites due to cancer. The number of patients with refractory liver ascites is forecast to increase dramatically due to the growing prevalence of NASH (Non-alcoholic Steatohepatitis).

Over 700 **alfa**pump systems have been implanted to date. The **alfa**pump has been endorsed by key independent third parties in Europe and has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for decompensated cirrhosis, the German treatment guidelines (DGVS) for complications of liver cirrhosis and the U.K. NICE interventional procedure guidance for treatment of refractory ascites caused by cirrhosis. In January 2019, the U.S. FDA granted Breakthrough Device designation to the **alfa**pump for the treatment of recurrent or refractory liver ascites. The Company expects to start POSEIDON, the North American pivotal study, in the second half of 2019 to support approval of the **alfa**pump in recurrent or refractory liver ascites.

Sequana Medical has leveraged its **alfa**pump experience and is developing **alfa**pump DSR (Direct Sodium Removal) to deliver a convenient and fully implanted system for DSR therapy, its novel and proprietary approach for the management of volume overload in patients suffering from heart failure. DSR therapy involves the removal of sodium via diffusion from the body into the peritoneal cavity by administering a sodium-free solution (DSR infusate) into the abdomen. The DSR infusate and the extracted sodium are then removed using the **alfa**pump and the body responds by eliminating the excess fluid via osmotic ultrafiltration (the movement of water, together with sodium, from the bloodstream to the peritoneal cavity) and/or urination. Volume overload in the body is a major clinical problem in heart failure, a condition that results in $13 billion of U.S. hospital admission costs annually.

Data from the first-in-human single dose DSR proof-of-concept study presented at Heart Failure 2019 demonstrated that DSR can result in the removal of large quantities of sodium and fluid in a safe and tolerable manner. The first clinical study of **alfa**pump DSR in patients with volume overload due to heart failure is expected to start in the second half of 2019.

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.*