Sequana Medical announces first patient enrolled in SAHARA DESERT

*alfa*pump® *DSR study in Heart Failure patients with persistent congestion*

Ghent, BELGIUM – 1 June 2021 – Sequana Medical NV (Euronext Brussels: SEQUA), an innovator in the treatment of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure, today announces that the first patient has been enrolled in the SAHARA DESERT study. Interim results are expected at the end of 2021 and top-line results in H2 2022.

Building on the strong results from RED DESERT[1], SAHARA DESERT is conducted in heart failure patients with residual congestion for whom oral diuretics are no longer effective at preventing fluid overload. The study will enrol 20 patients and will evaluate the ability of **alfa**pump DSR therapy to eliminate residual congestion, restore correct fluid status (euvolemia) and improve cardio-renal condition for up to 22 weeks.

Dr Oliver Gödje, Chief Medical Officer at Sequana Medical, commented: "We have been bold in developing our proprietary DSR (Direct Sodium Removal) therapy and the recent RED DESERT study results lead us to believe that DSR therapy, as long-term and short-term treatment, could be a breakthrough for the large number of heart failure patients with diuretic-resistant congestion. The SAHARA DESERT study will now assess **alfa**pump DSR therapy in decompensated heart failure patients, our intended patient population, for whom there are limited alternative treatment options."

Ian Crosbie, Chief Executive Officer at Sequana Medical, added: "As pioneers in the development of treatment options for diuretic-resistant fluid overload, we are very excited to start SAHARA DESERT. This study will enhance our understanding of how rapidly intensive DSR therapy can remove persistent congestion, improve diuretic response and cardio-renal function and how long these effects last whilst on maintenance DSR therapy. The removal of persistent congestion and improvement of cardio-renal function is a clear unmet clinical need in this large and growing patient population and we look forward to reporting interim results before year-end."

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

[1] Press release Top-line data RED DESERT - 11 May 2021

About SAHARA DESERT – alfapump **DSR study in decompensated heart failure patients**

SAHARA DESERT is a multi-centre, prospective, randomised, open-label study to evaluate the safety and feasibility of **alfa**pump DSR therapy in heart failure patients with persistent congestion and resistance to loop diuretic treatment. Twenty patients will be implanted with the **alfa**pump DSR system. Following **alfa**pump DSR implantation, patients will undergo a diuretic challenge to quantify their response to diuretics, which will be repeated at specific time points throughout the study. At the start of the study treatment period, loop diuretics will be withheld and patients will be randomised 1:1 to DSR therapy with or without SGLT2-inhibitor to evaluate their impact on DSR therapy. Patients will undergo intensive DSR therapy with DSR D10% infusate for two weeks (phase 1) which can be repeated up to two times depending on their euvolemic state, diuretic response and stable DSR dosing at the end of phase 1. Patients who have achieved euvolemia and have adequate diuretic response will enter into the maintenance DSR treatment phase with monthly DSR dosing for 16 weeks (phase 2).

The primary safety and tolerability endpoints include the rate of treatment-, device- or procedure-related serious adverse events through the end of the maintenance phase. Secondary feasibility endpoints include the ability of DSR therapy to restore and maintain euvolemia without the need for additional loop diuretic treatment. Additional exploratory endpoints will evaluate the potential impact of SGLT-2 inhibitors on DSR therapy. The study is being conducted in up to three clinical centres in the Republic of Georgia. For more information about the study, please visit clinicaltrials.gov (NCT04882358).

About alfapump **DSR in heart failure patients with diuretic-resistant congestion**

alfapump DSR is in clinical development as potential long-term treatment for heart failure patients with diuretic-resistant congestion. Congestion, also known as fluid overload, is the driver of more than 90% of the one million heart failure hospitalisations in the U.S. each year (which in total account for $13 billion in costs). The treatment options are severely limited in those patients for whom diuretics are no longer effective, which is evident from the 24% hospital re-admission rate at 30 days from discharge. Persistent congestion and worsening renal function is a key indicator of increased mortality in acute decompensated heart failure patients.

Sequana Medical's proprietary DSR therapy is a unique approach that removes sodium from the body using diffusion in the peritoneal cavity with the use of a sodium-free solution known as DSR infusate. Once the sodium has been removed, the body eliminates excess fluid naturally through urination to restore the serum sodium concentration. **alfa**pump DSR combines DSR therapy with the proven **alfa**pump to deliver a fully implanted system for long-term DSR therapy. Strong top-line results from the RED DESERT study showed that repeated dose **alfa**pump DSR therapy in diuretic-resistant heart failure patients is highly effective at managing the fluid and sodium balance and improves cardio-renal status. Following the six-week study, there was a dramatic improvement in patients' diuretic response and a meaningful long term reduction in their oral loop diuretic needs.

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. 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.

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.*

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.