Sequana Medical's results from RED DESERT alfapump DSR® study presented as one of the Highlights at Heart Failure 2021 Online Congress

Ghent, BELGIUM – 6 July 2021 – Sequana Medical NV (Euronext Brussels: SEQUA, the "Company" or "Sequana Medical"), an innovator in the treatment of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure, today announces that the positive results from its RED DESERT study of **alfa**pump DSR® (Direct Sodium Removal) which were presented at the Heart Failure 2021 Online Congress as part of the Late Breaking Science Results were also selected for the congress' Highlights session, held virtually on 1 July 2021.

Dr. Jeffrey Testani, Associate Professor of Medicine and Director of Heart Failure Research at Yale University School of Medicine, commented: "*It was an honour to present the results from the RED DESERT study at the Heart Failure 2021 Online Congress and to be included in the Highlights session. It is encouraging to see this recognition and we are thankful to the congress team. This elegant and innovative therapeutic approach of **alfa**pump DSR therapy demonstrated a significant improvement of cardio-renal function and a dramatic and sustained improvement in diuretic response.*"

alfapump DSR is Sequana Medical's proprietary therapy being developed for the treatment of diuretic-resistant congestion in heart failure patients. Strong results from the RED DESERT study in eight patients with diuretic-resistant heart failure were reported in May 2021, demonstrating that repeated **alfa**pump DSR therapy could effectively replace patients' high dose loop diuretics and restore their diuretic response and overall cardio-renal status.

Details of the presentation:

- Title: First in Human Experience with Alfapump DSR System in Diuretic Resistant Chronic Heart Failure
- Presenting: Dr. Jeffrey Testani
- A replay of the presentation is available on demand on the congress platform. To register, click here.
- A copy of the presentation is available on the website of Sequana Medical.

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

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. The SAHARA DESERT study of **alfa**pump DSR in decompensated heart failure patients with residual congestion is ongoing and will evaluate 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. Interim results are expected by end 2021 and top-line results in H2 2022.

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.*

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.