Sequana Medical receives MDSAP certification and expands its Quality Management System towards North America

Ghent, Belgium – 3 November 2021 – Sequana Medical NV (Euronext Brussels: SEQUA, the "Company"), an innovator in the treatment of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure, today announces it has received Medical Device Single Audit Program (MDSAP) certification from its auditing organisation British Standards Institution (BSI), thereby expanding its Quality Management System (QMS) towards the U.S. and Canada.

The MDSAP allows competent auditors of recognised auditing organisations, such as BSI, to conduct a single audit of a medical device manufacturer's QMS, which satisfies the requirements of the different regulatory jurisdictions participating to the programme (currently being Australia, Brazil, Canada, Japan and the U.S.). Sequana Medical's QMS has now been certified according to the ISO 13485:2016 criteria and the applicable requirements of the U.S. Food and Drug Administration (FDA) and Health Canada within the scope of *design, development, production and distribution of active implantable pump systems to transport fluids within the body.*

Timur Resch, Global Vice President QM/QA/RA at Sequana Medical, commented: "This MDSAP certification is a major accomplishment and we are very proud of having this globally certified QMS in place. We at Sequana Medical are fully committed to regulatory compliance and continuously keep our processes and approvals up to date with changing and increasing standards worldwide. We are now working hard towards securing the Medical Device Regulation (MDR) certification, the new regulatory framework for medical devices in Europe, for our **alfa**pump system."

Ian Crosbie, Chief Executive Officer at Sequana Medical, added: "This certification is a significant achievement for our quality and regulatory team and demonstrates the commitment of the entire organisation in pursuing the highest quality standards required by the different regulatory authorities. It forms an important element of the package required for **alfa**pump approval in the U.S. and Canada for patients with recurrent and refractory liver ascites. We look forward to completing enrolment in our North American pivotal POSEIDON study by the end of this year and reporting on the primary endpoint in Q4 2022 following the strong interim results reported earlier this year."

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 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, China, the EU, United Kingdom, and Hong Kong.*

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.