Sequana Medical receives certification under MDR, the new European Medical Device Regulation

***alfa**pump® is one of the first novel Class III active implantable medical devices to be certified*

Ghent, Belgium – 14 February 2022 – 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 it has received Medical Device Regulation (MDR) certification from its Notified Body, the British Standards Institution (BSI), ensuring continuous market access of the **alfa**pump system in the European Union (EU).

Sequana Medical was granted the EU Quality Management System (QMS) Certificate and the EU Technical Documentation Assessment Certificate confirming that the Company's QMS and the **alfa**pump system are compliant with the latest regulatory standards required for medical devices in Europe. The Company's proprietary DirectLink technology built into the **alfa**pump system has been classified as medical device under the MDR, clearly demonstrating the relevance and importance of **alfa**pump performance data monitoring, allowing physicians to closer follow-up on their patients. This announcement follows the recent QMS certification under the Medical Device Single Audit Program (MDSAP), demonstrating Sequana Medical's compliance to the high standards of medical device regulations internationally.

Timur Resch, Global Vice President QM/QA/RA at Sequana Medical, commented: *"Achieving MDR certification is another major milestone and the result of our early adaption to the new and more stringent regulatory requirements in Europe. This achievement would not have been possible without the extensive and diligent work of the entire Sequana Medical team. We are also very thankful for the longstanding relationship with BSI, our competent Notified Body, and we look forward to continuing working with them."*

Ian Crosbie, Chief Executive Officer at Sequana Medical, added: *"Without doubt, MDR has raised the standards for medical device regulation and we are excited to be one of the first novel Class III active implantable medical device companies to receive this certification. It shows our strong commitment to complying with the highest regulatory standards for medical devices and is a demonstration of our progress to meeting the standards required for approval of the **alfa**pump in the U.S."*

About European Medical Device Regulation (MDR)

The MDR 2017/745 came into effect in May 2021, replacing the former European Directives for medical devices (AIMDD 90/385/EEC and MDD 93/42/EEC). It is intended to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices to ensure a high level of safety and health whilst supporting innovation. MDR has significantly increased the requirements in respect of technical documentation, benefit-risk evaluation, Unique Device Identification (UDI), Economic Operators, clinical data and post-market surveillance, with more stringent scrutiny of Competent Authorities and Notified Bodies. It represents the biggest change in European medical device compliance standards in more than 20 years.

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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 Sequana Medical's 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 and a rapid and persistent clinically important improvement in quality of life. All patients have been enrolled in the study and primary endpoint reporting is planned for Q4 2022. 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 900 **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 demonstrated that repeated DSR therapy in diuretic-resistant heart failure patients is able to manage their fluid and sodium balance, improve their cardio-renal status and restore their diuretic response for months post-treatment.

Interim results from the ongoing SAHARA DESERT study of **alfa**pump DSR in decompensated heart failure patients indicated a safe, effective and rapid elimination of persistent congestion and restoration of euvolemia, together with a considerable benefit in cardio-renal status and a dramatic improvement in diuretic responsiveness. Reporting of top-line data is planned for H2 2022.

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.