Sequana Medical announces additional patents for DSR® in China and the United States

Ghent, Belgium – 22 March 2023 – Sequana Medical NV (Euronext Brussels: SEQUA) (the "**Company**" or "**Sequana Medical**"), a pioneer in the treatment of fluid overload in liver disease, heart failure and cancer, today announces further strengthening of the intellectual property portfolio for its DSR (Direct Sodium Removal) program. A key composition of matter patent was allowed in China and an additional patent on the method of operation was granted in the US.

Chinese patent application number 201880045801.6 was allowed on 7 March 2023. This key patent entitled "Direct sodium removal method, solution and apparatus to reduce fluid overload in heart failure patients" has already been granted in the US and Europe and is pending in other regions such as Australia, Canada and Japan. It protects the use of a sodium-free or low-sodium infusate that is administered into a patient's peritoneal cavity to directly remove sodium, and thereby fluid from the body to alleviate fluid overload in heart failure patients with residual renal function.

US patent number 11,602,583 B2 was granted on 14 March 2023 and covers the expansion of the method of operation for Sequana Medical's DSR therapy using an implantable pump system. While the Company's current focus is on Short Term DSR therapy using a peritoneal catheter, the additional US patent granted gives further flexibility to use implantable pump systems, such as its **alfa**pump®, to provide patients with long-term support.

To date, Sequana Medical has filed 16 patents for its DSR program of which 6 have been granted, covering a broad range of aspects, both for the method of operation and composition of matter.

Ian Crosbie, Chief Executive Officer of Sequana Medical, commented: *"As the evidence for DSR's disease-modifying effect in heart failure grows, we continue to build a strong patent portfolio for our DSR program and the patent allowed in China is an important international reinforcement of that. Cardiovascular disease is the leading cause of healthcare burden in China with 4.5 million people suffering from heart failure.[1] The Chinese market offers huge potential for DSR where we believe it represents a compelling treatment option in this large and growing heart failure market.*

"Following the long-lasting clinical benefits observed in our RED DESERT and SAHARA proof-of-concept studies, we are focusing on Short Term DSR therapy using a peritoneal catheter. Use of DSR therapy with an implantable pump system such as our ***alfa****pump could be of great relevance in particular populations of congestive heart failure patients requiring regular DSR therapy. Today's announcement gives this approach further strong patent protection."*

[1] Weiwei et al., European Heart Journal Supplements (2016), European Society of Cardiology

For more information, please contact:

Sequana Medical

Lies Vanneste
Director Investor Relations
E: IR@sequanamedical.com
T: +32 (0)498 053579

Optimum Strategic Communications
Nick Bastin, Jonathan Edwards, Vici Rabbetts
E: Sequana@optimumcomms.com
T: +44 (0) 208 078 4357

About DSR in congestive heart failure

Sequana Medical considers its proprietary DSR to be a disease modifying therapy for congestive heart failure. Fluid accumulation in heart failure patients is caused by the retention of too much sodium. The DSR drug-based approach directly tackles this key clinical problem of sodium overload, and works in partnership with the kidneys to safely and rapidly eliminate the excess fluid. Complementary to existing heart failure therapies, clinical proof-of-concept studies using the Company's first-generation DSR product (DSR 1.0) have shown that DSR can i) safely, effectively and rapidly eliminate fluid overload in heart failure patients, ii) improve the health of the heart and preserve renal function, and iii) restore the ability of the kidney to manage the fluid and sodium naturally, resulting in a large and long-lasting reduction in the need for diuretic drugs. In DSR treated patients, there have been no congestion-related re-hospitalizations during the study follow-up period, all patients improved their NYHA status by at least one class and the clinical benefits observed in the clinical studies resulted in a 75% reduction in predicted one-year mortality of patients pre- vs. post-intensive DSR therapy based on the Seattle Heart Failure Model. The Company is currently preparing an IND application for its second-generation DSR product (DSR 2.0) in the US and plans to begin a US randomized controlled Phase 1/2a clinical trial in Q2 2023.

About Sequana Medical

Sequana Medical NV is a pioneer in treating fluid overload, a serious and frequent clinical complication in patients with liver disease, heart failure and cancer. These patients can have up to 15 liters of extra fluid in their bodies, causing major medical issues including increased mortality, repeated hospitalizations, severe pain, difficult breathing and restricted mobility that severely impacts daily life. Although diuretics are standard of care, the problem is that in many patients they are no longer effective and / or tolerable. There are limited effective treatment options for these patients, resulting in poor clinical outcomes, high costs and a major impact on their quality of life. Sequana Medical is seeking to provide innovative treatment options for this large and growing "diuretic-resistant" patient population.

alfapump® and DSR® are Sequana Medical's proprietary platforms that work with the body to treat diuretic-resistant fluid overload, delivering major clinical and quality of life benefits for patients and reducing costs for healthcare systems. The Company has reported positive primary endpoint data from the North American pivotal POSEIDON trial of the **alfa**pump in recurrent or refractory ascites due to liver cirrhosis, enabling the filing of a Pre-Market Approval (PMA) application with the FDA, planned for H2 2023. Having delivered clinical proof-of-concept for DSR as a disease-modifying drug program for the treatment of heart failure, the Company is planning to commence MOJAVE, a US multi-centered randomized controlled Phase 1/2a clinical trial of DSR 2.0, in Q2 2023.

Sequana Medical is listed on Euronext Brussels (Ticker: SEQUA.BR) and headquartered in Ghent, Belgium. For further information, please visit www.sequanamedical.com.

Important Regulatory Disclaimers

*The **alfa**pump® system is currently not approved in the United States or Canada. In the United States and Canada, the **alfa**pump system is currently under clinical investigation (POSEIDON Trial) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical trial see www.poseidonstudy.com. 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. DSR therapy is currently not approved for clinical research in the United States or Canada. There is no link between 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® is a registered trademark 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.