Sequana Medical announces the successful completion of pre-clinical studies with its second-generation DSR product for congestive heart failure

- **Data from GLP[i] animal studies demonstrate safety of second-generation DSR[ii] product (DSR 2.0)**
- **Data from Phase 1 study of DSR 2.0 in Mexico (CHIHUAHUA) and IND[iii] filing to US FDA expected in Q1 2023**
- **Planning to start MOJAVE, a US Phase 1/2a randomized controlled multi-center study of DSR 2.0, in Q2 2023**

Ghent, Belgium – 08 February 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 the successful completion of its GLP animal studies, demonstrating the safety of its second-generation DSR product (DSR 2.0), following chronic exposure. These animal data, together with the data from the Phase 1 CHIHUAHUA study, are intended to support the US IND filing of DSR 2.0. FDA approval of the US IND will enable the Company to start MOJAVE, its randomized, controlled, multi-center Phase 1/2a US study of DSR 2.0, planned for Q2 2023.

The GLP studies were conducted on 30 healthy mice and 18 healthy sheep. Each animal study comprised of three study groups which included one control group using standard peritoneal dialysis (PD) solution and two test groups using Sequana Medical's proprietary DSR 2.0 product. The test groups consisted of one group being given the anticipated maximum standard dose and one group being given double of the maximum dose. The mice were exposed for 30 days, resembling their average life time, and the sheep were exposed for up to 45 days.

The purpose of these GLP studies was to evaluate the chronic exposure of DSR 2.0 on animal health and tissue of peritoneum, kidneys, omentum, and peritoneal cavity. Data from both studies reported that no difference in systemic and local toxic effects were observed in animals treated repeatedly with DSR 2.0, compared to animals in the control group, concluding that DSR 2.0 had consistent safety with the standard PD solution.

Oliver Gödje, Chief Medical Officer at Sequana Medical, commented: *"We are pleased to see these positive animal data of our second-generation DSR product, which is designed to deliver therapeutic and safety benefits over the first-generation DSR product. We have previously reported impressive clinical results from the SAHARA study with DSR 1.0 as a potential disease-modifying heart failure therapy, and we look forward to commencing MOJAVE, the first randomized controlled multi-center study in the US using DSR 2.0."*

<u>On track to start MOJAVE with DSR 2.0 in Q2 2023</u>

The Company is progressing the development of its proprietary DSR 2.0 product, a sodium-free dextrose / icodextrin solution expected to have an improved therapeutic and favourable safety profile, and robust intellectual property protection. Two ongoing Phase 1 interventional, single-centre, single-arm studies, one in Canada (YUKON) and one in Mexico (CHIHUAHUA), are evaluating the safety, tolerability and efficacy of DSR 2.0 and are expected to each enroll up to ten stable peritoneal dialysis patients to receive a single treatment of DSR 2.0, administered through their peritoneal dialysis catheter. The choice of peritoneal dialysis patients is

driven by their pre-existing peritoneal dialysis catheter. Data from the GLP animal and Phase 1 CHIHUAHUA studies are intended to support the filing of the US IND, planned for Q1 2023.

Following several initial discussions with the FDA, MOJAVE, a randomized controlled Phase 1/2a US study of DSR 2.0, is on track to start in Q2 2023, assuming FDA approval of the US IND application. The intention is to enrol 30 diuretic-resistant chronic heart failure patients with persistent congestion, with 20 patients randomized to DSR 2.0 administered via a peritoneal catheter on top of usual care for congestive heart failure (CHF) for up to four weeks and ten patients randomized to intravenous loop diuretic treatment as part of maximized usual care for CHF alone. Following four weeks of treatment, there will be a three-month safety follow-up period. Prior to enrolment of these 30 patients, the intention is for three additional patients to be enrolled in a non-randomized safety cohort and to receive DSR 2.0 administered via a peritoneal catheter on top of CHF usual care for up to four weeks. Progression to the enrolment of the 30 randomized patients will be dependent upon DSMB[iv] approval following their review of the initial three patients. More details on the final study design will be announced following the FDA approval of the US IND application. Interim data of MOJAVE are expected in H2 2023 followed by top-line results in H2 2024.

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About fluid overload in heart failure (AKA congestion)

Heart failure is the leading cause of US hospitalizations in patients over 65 years old and 90% of these admissions are due to fluid overload, which is recognized as the primary driver of morbidity and hospitalization. Standard of care includes treatment with diuretic drugs, but these have well-recognized toxicity and resistance issues. Half of the heart failure patients admitted for fluid overload are discharged with no clinically relevant loss of fluid and one in four is re-admitted to the hospital within 30 days of discharge. It is estimated that 200,000 of US heart failure patients have drug-resistant congestion requiring repeated hospitalization, severely impacting their survival and quality of life and creating a heavy financial burden.

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 study 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 study 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 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. 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.

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[i] GLP: Good Laboratory Practices
[ii] DSR: Direct Sodium Removal
[iii] IND: Investigational New Drug
[iv] DSMB: Data and Safety Monitoring Board