Sequana Medical announces positive results from CHIHUAHUA, Phase 1 clinical trial of second-generation DSR product for congestive heart failure

- **Phase 1 clinical trial (CHIHUAHUA) demonstrates that single dose of second-generation DSR product (DSR 2.0) is safe and well-tolerated, and indicates a compelling dosing profile**
- **On track to file IND[i] application to US FDA in Q1 2023**
- **Start of MOJAVE, a US multi-center randomized controlled Phase 1/2a clinical trial of DSR 2.0, planned for Q2 2023**

Ghent, Belgium – 01 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 positive results from its Phase 1 single-center, single-arm, single-dose trial (CHIHUAHUA) with its second-generation DSR product (DSR 2.0).

This Phase 1 trial was conducted in ten stable peritoneal dialysis patients, who received a single treatment of Sequana Medical's proprietary DSR 2.0 product, administered via their pre-existing peritoneal dialysis catheter, over a 24-hour dwell period. The purpose of the trial was to evaluate the safety and tolerability profile of DSR 2.0, as well as to understand the dosing dynamics of DSR 2.0.

DSR 2.0 was generally safe and well-tolerated, with no serious adverse events or discontinuations due to adverse events. No patient showed a clinically relevant change in serum sodium levels or progressive hyponatremia, a further proof of safety of DSR 2.0. On average, a total of approximately 3L of fluid was removed per patient including 9g of sodium following a single treatment with 0.5L DSR 2.0 and a 24-hour dwell period.

Oliver Gödje, Chief Medical Officer of Sequana Medical, commented: *"The results of this study are really encouraging and, together with the positive safety data from the GLP[ii] studies reported earlier this month, enable the filing of our IND application with the US FDA for MOJAVE, our US randomized controlled Phase 1/2a clinical trial, planned to start in Q2 2023.*

"In addition to positive safety and tolerability findings, with no serious adverse events or discontinuations, the amount of fluid and sodium removed following a single treatment is an indication of the effectiveness of DSR 2.0 as a potential treatment for patients with congestive heart failure."

<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 that is expected to have an improved therapeutic and favourable safety profile, and robust intellectual property protection. Data from the GLP animal studies[iii] and Phase 1 CHIHUAHUA study are intended to support the filing of the US IND application, planned for Q1 2023.

Following several initial discussions with the FDA, MOJAVE, a US multi-center randomized controlled Phase 1/2a clinical trial of DSR 2.0, is on track to start in Q2 2023, assuming FDA approval of the IND application. The intention is to enrol 30 diuretic-resistant chronic heart failure patients with persistent congestion. Of these, 20 randomized patients will receive 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 randomized patients will receive 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 is anticipated to be dependent upon DSMB[iv] approval following their review of the initial three patients. More details on the final trial 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 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 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.

[i] IND: Investigational New Drug
[ii] GLP: Good Laboratory Practices
[iii] Data reported in press release of 8 February 2023
[iv] DSMB: Data and Safety Monitoring Board