Sequana Medical announces first patient enrolled in MOJAVE, a US randomized controlled Phase 1/2a study of DSR® 2.0 for treatment of congestive heart failure

- **US study seeking to confirm strong efficacy data reported in RED DESERT and SAHARA**
- **Initial data expected in Q4 2023**

Ghent, Belgium – 10 July 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 that the first patient has been enrolled in its MOJAVE study.

MOJAVE, a randomized controlled Phase 1/2a study in the US, will evaluate the safety and efficacy of the Company's second-generation DSR product (DSR 2.0) in diuretic-resistant chronic heart failure patients with persistent congestion. The study will start with a non-randomized cohort of three patients treated with DSR 2.0. Progress to the randomized cohort of up to 30 additional patients depends on approval from the Data and Safety Monitoring Board (DSMB) following their review of the non-randomized cohort data, planned for Q4 2023.

Oliver Gödje, Chief Medical Officer of Sequana Medical, commented: *"We are excited to commence this important study that builds on the strong clinical evidence already reported for our DSR program. With our MOJAVE study, we seek to confirm the strong safety and efficacy data observed in our RED DESERT and SAHARA studies and look forward to reporting data from the first three patients by end of the year."*

Ian Crosbie, Chief Executive Officer of Sequana Medical, commented: *"Heart failure is the leading cause of US hospitalizations in patients over 65 years old, with approximately one million admissions each year of which 90% are due to symptoms of fluid overload. Diuretic-resistance is widespread with nearly half of these patients leaving hospital with persistent congestion, and one in four readmitted within 30 days of discharge. There is an urgent need for new therapies that safely and effectively eliminate congestion and improve clinical outcomes, and we believe DSR has the potential to be a disease-modifying heart failure therapy for these patients."*

MOJAVE study design

The non-randomized cohort consists of three eligible patients who will be treated with DSR 2.0, administered via a peritoneal dialysis (PD) catheter, on top of optimized usual care for congestive heart failure for up to four weeks, followed by a three-month safety follow-up period.

Following review and approval of the non-randomized cohort data by the DSMB, patients will be enrolled in the multi-center randomized cohort. The intention is for up to 20 randomized patients to be treated with DSR 2.0, administered via a PD catheter, on top of optimized usual care for congestive heart failure for up to four weeks and for up to ten randomized patients treated with intravenous loop diuretics alone as part of maximized usual care for congestive heart failure. Following four weeks of treatment, there is a three-month safety follow-up period.

Primary and secondary safety and efficacy endpoints include the rate of adverse and serious adverse events and the improvement in diuretic response (measured as a six-hour urine sodium output) from baseline through the end of the treatment period. Exploratory endpoints measured from baseline through the end of the

treatment period include change in weight (volume status), creatinine (a marker of renal function), natriuretic peptides (a marker of heart failure) and New York Heart Association (NYHA) functional class; and the number of heart failure related rehospitalizations.

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About DSR in congestive heart failure

Sequana Medical is developing its proprietary DSR as a disease-modifying therapy for congestive heart failure. Fluid overload (AKA congestion) in heart failure patients is caused by the retention of sodium and the DSR drug-based approach directly tackles this key clinical problem by working in partnership with the kidneys and is complementary to existing heart failure therapies.

Clinical proof-of-concept studies in diuretic-resistent heart failure patients using the Company's first-generation DSR product (DSR 1.0) have shown:

i) safe, effective and rapidly elimination of fluid overload
ii) improvement in cardiovascular status and preservation of renal function, and
iii) restoration of diuretic response and the ability of the kidney to manage fluid status 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 periods, 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.

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,

difficulty 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 has commenced MOJAVE, a US randomized controlled multi-center Phase 1/2a clinical trial of DSR 2.0, with initial data expected in Q4 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 liver cirrhosis. 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. 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® and DSR® are registered trademarks.*

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.