Sequana Medical announces FDA clearance of IND application for DSR® 2.0 for treatment of congestive heart failure

- **MOJAVE study on track to start in Q2 2023 as planned, with initial data by year-end**
  - **Randomized, controlled study in US seeking to confirm strong efficacy data seen in RED DESERT and SAHARA studies**
- **DSR well positioned as disease-modifying heart failure therapy**

Ghent, Belgium – 02 May 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 US Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for its second-generation DSR product (DSR 2.0) for the treatment of congestive heart failure. This enables the Company to initiate its randomized controlled Phase 1/2a MOJAVE study in the US, in Q2 2023 as planned.

Oliver Gödje, Chief Medical Officer of Sequana Medical, commented: *"We are delighted to obtain clearance of the IND for our DSR 2.0 product and are ready to commence the MOJAVE study in US patients with congestive heart failure in a timely manner. We are now focused on enrolling our first patient, which we expect will occur in the second quarter of 2023, and look forward to reporting data from the three patients of the non-randomized cohort by year-end."*

Ian Crosbie, Chief Executive Officer of Sequana Medical, added: *"For the estimated 200,000 diuretic-resistant congestive heart failure patients in the US, there is an urgent need for new therapies that can safely and effectively eliminate congestion, reduce repeated hospitalization and improve clinical outcomes. Following the strong safety and efficacy data reported from our RED DESERT and SAHARA proof-of-concept studies, we believe that our DSR therapy has the potential to be a disease-modifying heart failure therapy."*

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

MOJAVE is a randomized controlled Phase 1/2a study in the US, designed to evaluate the safety and efficacy of DSR 2.0 in diuretic-resistant chronic heart failure patients with persistent congestion.

Following Ethics Committee approval, the study will commence with a non-randomized cohort of three eligible patients treated with DSR 2.0, administered via a peritoneal dialysis (PD) catheter, on top of usual care for congestive heart failure for up to four weeks followed by a three-month safety follow-up period. Progress to the randomized cohort of up to 30 additional patients depends on approval from the Data and Safety Monitoring Board (DSMB) following review of the non-randomized cohort data.

The randomized cohort consists of up to 20 randomized patients treated with DSR 2.0, administered via a PD catheter, on top of usual care for congestive heart failure for up to four weeks and 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 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.

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 will commence 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 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. 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.