Sequana Medical announces submission of Investigational New Drug (IND) application for DSR® 2.0 for treatment of congestive heart failure

Ghent, Belgium – 03 April 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 it has submitted an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) on 31 March 2023 for its second-generation DSR product (DSR 2.0) for the treatment of congestive heart failure. Clearance of the IND will pave the way for the Company to initiate its randomized controlled Phase 1/2a MOJAVE study in the US, planned for Q2 2023.

The IND application includes data from the previously reported GLP animal[1] and Phase 1 CHIHUAHUA[2] studies supporting the safety and tolerability profile of Sequana Medical's DSR 2.0 product, as well as the strong safety and efficacy data reported from RED DESERT and SAHARA proof-of-concept studies with its first-generation DSR product (DSR 1.0). Additionally, the application also contains manufacturing information of DSR 2.0 and an outline of the MOJAVE study design.

Oliver Gödje, Chief Medical Officer of Sequana Medical, commented: *"Today's announcement is an important milestone for our DSR program. There are an estimated 200,000 US heart failure patients suffering from diuretic-resistant congestion that requires repeated hospitalization at an estimated cost of $14bn a year, and therefore an urgent need for new therapies such as DSR to alleviate this burden and improve patients' lives. We are very excited to build upon the exciting results from our RED DESERT and SAHARA studies and bring our second generation product, DSR 2.0 into the clinic in the US. We look forward to reporting data from the first US patients later this year."*

On track to start MOJAVE with DSR 2.0 in Q2 2023

The final study design of the randomized controlled Phase 1/2a MOJAVE study in the US will be communicated upon approval by the FDA and Ethics Committees. Following several initial discussions with the FDA, 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 for up to four weeks and ten randomized patients will receive intravenous loop diuretic treatment as part of maximized usual care for congestive heart failure 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 patients to be enrolled in a non-randomized safety cohort and to receive DSR 2.0 administered via a peritoneal catheter on top of congestive heart failure usual care for up to four weeks. Advancing to the enrolment of the 30 randomized patients is anticipated to be dependent upon DSMB[3] approval following their review of the initial three patients.

[1] Data announced in press release on 8 February 2023
[2] Data announced in press release on 1 March 2023
[3] DSMB: Data Safety Monitoring Board

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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. The Company plans to begin MOJAVE, 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, 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 is planning to commence MOJAVE, a US randomized controlled multi-center 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® 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.