

Strong data from DSR® proof-of-concept studies in heart failure accepted for late-breaking presentation at THT 2024

Presentation by Key Opinion Leader Dr. Testani on Wednesday, March 6th 2024

Ghent, Belgium – 28 February 2024 – 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 late-breaking abstract including data from the RED DESERT and SAHARA proof-of-concept studies of the Company's DSR therapy in patients with diuretic-resistant heart failure have been selected for a late-breaking presentation at [THT 2024](#).

Technology and Heart failure Therapeutics (THT) will be held from March 4th to 6th, 2024 in Boston, US and is an international conference on the latest heart failure innovations, focusing on device- and technology-based treatments within the context of drug therapies.

The abstract "Serial Direct Sodium Removal in Patients with Heart Failure and Diuretic Resistance" will be presented on Wednesday March 6th, 2024 by Dr. Jeffrey Testani, Associate Professor of Medicine and Director of Heart Failure Research at Yale University School of Medicine and will become available on the website of THT prior to the start of the conference.

For more information, please contact:

Sequana Medical

Lies Vanneste

Director Investor Relations

E: IR@sequanamedical.com

T: +32 (0)498 053579

About DSR, a disease-modifying heart failure drug therapy tackling cardiorenal syndrome (CRS)

Cardiorenal syndrome is a key clinical challenge in heart failure and results from the combined vicious cycle of dysfunction of the heart and kidney. Despite the complex pathophysiology, the resultant clinical profile is thought to manifest as a self-reinforcing negative feedback cycle characterized by decreased glomerular filtration, increased renal sodium avidity, and congestion, despite escalating diuretic doses.

No current therapies have been shown to improve patient outcomes in this complex and poorly understood indication. Reducing congestion is a key element of therapy but loop diuretics exacerbate many of the core mechanisms thought to underly CRS. Through effective control of the volume status for an extended period of time and thereby avoiding the negative consequences of loop diuretics, DSR has the potential to break the negative feedback cycle of this clinical challenge.

Extensive analysis of patients in the RED DESERT and SAHARA studies shows the benefit from DSR therapy on i) volume status, ii) normalized diuretic response and dramatically reduced loop diuretic dosing, iii) improvement in kidney function, iv) neurohormonal status and signalling, as well as v) cardiovascular

parameters. In these patients there were no congestion-related re-hospitalizations, a one class improvement in their NYHA status and a reduction of 75% in their predicated one-year mortality (based on the Seattle Heart Failure model). Initial data from the non-randomized cohort in the US MOJAVE study support these findings and indicated that DSR is safe and well tolerated, restores diuretic response and improves cardio-renal health.

Data from the RED DESERT and SAHARA proof-of-concept studies have been submitted for publication in a peer-reviewed journal.

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. This causes major medical issues including increased mortality, repeated hospitalizations, severe pain, difficulty breathing and restricted mobility. Although diuretics are standard of care, they become ineffective, intolerable or exacerbate the problem in many patients. There are limited effective treatment options, 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's Premarket Approval (PMA) application for the **alfapump** was submitted to the US FDA in December 2023 and accepted for substantive review in January 2024, having reported positive primary and secondary endpoint data from the North American pivotal POSEIDON study in recurrent or refractory ascites due to liver cirrhosis. US market approval of the **alfapump** is anticipated in the second half of 2024.

Results of the Company's RED DESERT and SAHARA proof-of-concept studies in heart failure support DSR's mechanism of action as breaking the vicious cycle of cardiorenal syndrome. All three patients from the non-randomized cohort of MOJAVE, a US randomized controlled multi-center Phase 1/2a clinical study, have been successfully treated with DSR, confirming the strong clinical outcomes seen in the RED DESERT and SAHARA studies. The independent Data Safety Monitoring Board approved the start of the randomized MOJAVE cohort of up to a further 30 patients, which is planned after **alfapump** PMA approval.

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 **alfapump**[®] system is currently not approved in the United States or Canada. In the United States and Canada, the **alfapump** 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 **alfapump** system in Europe, the United States or Canada.*

Note: **alfapump**[®] 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.