PRESS RELEASE
REGULATED INFORMATION
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Sequana Medical Announces Granting of Key Additional U.S. Patent for DSR

- ***Builds upon existing granted DSR patents in US, Europe, Japan and China***
- ***Strengthens DSR patent protection based upon extensive clinical and pre-clinical experience***
- ***Data published in European Journal of Heart Failure supports DSR as breakthrough in treatment of cardiorenal syndrome and diuretic-resistant heart failure***
- ***US MOJAVE clinical study of DSR vs IV loop diuretics planned to enter randomized controlled phase following dedicated DSR financing***

Ghent, Belgium – 18 December 2025 – Sequana Medical NV (Euronext Brussels: SEQUA, the "Company" or "Sequana Medical"), a pioneer in the treatment of drug-resistant fluid overload in liver disease, heart failure and cancer, today announces the granting of a key additional US patent for the DSR (Direct Sodium Removal) programme. DSR is Sequana Medical's drug development program for the treatment of cardiorenal syndrome and diuretic-resistant heart failure.

U.S. patent number 12,496,384 B2 is entitled *"Formulations and Methods for Direct sodium removal in patients having heart failure and/or severe renal dysfunction"* and covers the DSR infusate and its method of operation. Specifically, it covers the use of a no or low sodium infusate that is administered to a patient's peritoneal cavity to directly remove sodium, and thereby fluid from the body to alleviate fluid overload in heart failure patients with residual renal function.

Ian Crosbie, Chief Executive Officer at Sequana Medical, commented: "We are very pleased with the granting of this additional US patent, which we believe provides significant additional protection for our DSR programme. This patent builds upon our extensive pre-clinical and clinical experience of DSR, including the RED DESERT and SAHARA studies and strengthens the protection for our second generation DSR infusate. This is the formulation for the US MOJAVE randomised controlled study and the one that we believe can deliver significant clinical benefits to clinicians and patients, as well as commercial benefits to the Company. We continue to believe that DSR represents a potential breakthrough in the treatment of cardiorenal syndrome and diuretic-resistant heart failure, and look forward to resuming the MOJAVE study following completion of dedicated financing."

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DSR® therapy is still in development and is currently not approved in any country. The safety and effectiveness of DSR® therapy has not been established.

Note: **alfa**pump® and DSR® are registered trademarks.

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

Fluid overload in heart failure, AKA congestion, is a key clinical challenge. 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.

Congestion remains a key clinical challenge with US heart-failure related hospitalisation costs estimated at over $14 billion, and over 90% of these hospitalisations being due to congestion. Approximately 1 in 4 of these patients are readmitted within 30 days of discharge due to the limitations of current therapy.

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). These results were published in the European Journal of Heart Failure.

Initial data from the initial 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.

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. **alfa**pump® and DSR® are Sequana Medical’s proprietary platforms that work with the body to treat diuretic-resistant fluid overload, and are intended to deliver major clinical and quality of life benefits for patients, while reducing costs for healthcare systems.

The Company received US FDA approval for the **alfa**pump System for the treatment of recurrent or refractory ascites due to liver cirrhosis in December 2024, following the grant of FDA Breakthrough Device

Designation in 2019. In Sequana Medical's POSEIDON study, a landmark study across 18 centers in the US and Canada, the pivotal cohort of 40 patients implanted with the **alfa**pump showed at 6 and 24 months post-implantation the virtual elimination of therapeutic paracentesis and an improvement in quality of life[1, 2].

Sequana Medical is commercializing the **alfa**pump through a specialty commercial team initially targeting US liver transplant centers – 90 of these centers perform more than 90% of US liver transplants annually. In August 2025, CMS announced that it approved the New Technology Add-on Payment for the **alfa**pump when performed in the hospital inpatient setting as of October 1, 2025.

Results of the Company's RED DESERT and SAHARA proof-of-concept studies in heart failure published in European Journal of Heart Failure in April 2024 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, resulting in a dramatic improvement in diuretic response and virtual elimination of loop diuretic requirements.[3] The independent Data Safety Monitoring Board approved the start of the randomized MOJAVE cohort of up to a further 30 patients, which is dependent on securing additional financing.

Sequana Medical is listed on the regulated market of Euronext Brussels (Ticker: SEQUA.BR) and headquartered in Ghent, Belgium. For further information, please visit www.sequanamedical.com.

Important Safety Information: For important safety information regarding the **alfa**pump® system, see https://www.sequanamedical.com/wp-content/uploads/ISI.pdf.

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.

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[1] ***alfa****pump system SSED (summary of safety and effectiveness) PMA 230044*

[2] *as defined by subjective physical health (assessed by SF-36 PCS) and ascites symptoms (assessed by Ascites Q)*

[3] Data reported in press release of March 25, 2024; mean increase of 326% in six-hour urinary sodium excretion at 3 months follow up vs baseline, and 95% reduction of loop diuretics over same period