PRESS RELEASE
REGULATED INFORMATION – INSIDE INFORMATION
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Sequana Medical announces positive outcome of Day 100 meeting with FDA regarding PMA application for alfapump®

Positive and collaborative meeting with FDA

PMA substantive review complete; No further new questions on clinical or pre-clinical data

FDA Advisory Panel no longer expected

FDA Marketing Approval now anticipated in Q1 2025

Planned US commercial launch remains H2 2025

Ghent, Belgium – 22 May 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 the agreed outcome of the "Day 100" meeting[i] with the US Food and Drug Administration (FDA), following receipt of the "Day 90" major deficiency Letter. The **alfa**pump is the Company's fully implantable, wirelessly charged device for patients with recurrent or refractory ascites due to liver cirrhosis and received breakthrough device designation from the US FDA in 2019.

The PMA application for the **alfa**pump system, which was based on the successful execution of Sequana Medical's pivotal POSEIDON study, was accepted for substantive review on 29 January 2024. Following a review of this application by the FDA, the Company received a "Day 90" major deficiency letter and a "Day 100" meeting was held with FDA to align on key findings. The FDA confirmed completion of the substantive review and no further new questions on the clinical study or the pre-clinical data, unless related to the Company's response to the "Day 90" Letter. The FDA had a number of non-clinical questions that require additional work and the Company currently anticipates to submit this additional information by the end of September 2024. In light of the FDA's feedback and the rapidly evolving cybersecurity environment, the Company intends to exclude RPMS/DirectLink (the software for remote uploading of performance data from the alfapump) from the PMA application and the initial **alfa**pump commercialisation, and to submit a next-generation version in a PMA supplement post-approval.

The Company now forecasts FDA approval before the end of Q1 2025, with no change to the planned US commercial launch in H2 2025. The Company continues to evaluate its financing options to achieve FDA approval and prepare for commercial launch of the **alfa**pump.

Timur Resch, Global Vice President QM/QA/RA at Sequana Medical, commented: *"The receipt of the PMA Day 90 letter and completion of the Day 100 meeting is another huge milestone for Sequana, and reflects the significant amount of work by the team for the preparation of the marketing application. We appreciate the positive interaction with the FDA and believe that the outstanding questions are manageable. We intend to complete these activities in time for a response to the FDA by the end of Q3 this year."*

Ian Crosbie, Chief Executive Officer of Sequana Medical, commented: *"We are very pleased with the progress of our **alfa**pump PMA application and grateful for the collaborative nature of discussions with the FDA for our breakthrough device. The completion of the substantive review and confirmation there will be no further new questions related to the clinical study data or pre-clinical data, unless related to our responses, is a very important event for us, providing clarity on the approval path forward and derisking the **alfa**pump program. We look forward to addressing the remaining questions from FDA and anticipate approval before the end of Q1 2025."*

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About alfapump in recurrent or refractory ascites due to liver cirrhosis

Recurrent or refractory ascites is a severe condition characterized by the accumulation of fluid in the abdomen. The current standard treatment involves therapeutic paracentesis, an invasive and burdensome procedure that drains ascites from the abdomen using a large needle over an extended period. If approved by the FDA, the **alfa**pump could become the first active implantable medical device in the US that automatically and continuously removes ascites from the abdomen into the bladder, where it is naturally eliminated through urination.

The PMA application submitted to the US FDA was based on the successful execution of Sequana Medical's pivotal POSEIDON study, a landmark study across 18 centers in the US and Canada with a total of 69 patients implanted with the **alfa**pump. The primary effectiveness endpoints at six months post-implantation in the Pivotal Cohort[ii] exceeded the predefined thresholds with statistical significance, and primary safety endpoint data was in line with expectations[iii]. Data at 12 months post-implantation continued to show a strong and durable clinical profile, virtually eliminating the need for therapeutic paracentesis and delivering a clinically meaningful improvement in patients' quality of life[iv].

Data from the patient preference study and a matched cohort analysis of the NACSELD-III registry with the POSEIDON Pivotal Cohort indicated that US patients have a strong preference for the **alfa**pump vs standard paracentesis procedures and that the safety profile of the **alfa**pump is comparable to standard of care.

The North American market of recurrent and refractory ascites due to liver cirrhosis is forecast to grow on average 9% per year, from approximately 78,000 patients in 2025 reaching 147,000 patients by 2032, primarily driven by the increasing prevalence of NASH[v]. The total market opportunity for **alfa**pump is estimated at $2.4 billion in 2025, including approximately $600 million from the Company's initial priority market targeting patients requiring at least 12 paracentes per year. To date, over 1,000 **alfa**pump systems have been implanted.

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, untolerable 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, 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 **alfa**pump 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 **alfa**pump is anticipated before the end of Q1 2025 with US commercial launch planned for H2 2025.

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, resulting in a dramatic improvement in diuretic response and virtual elimination of loop diuretic requirements. 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 **alfa**pump US PMA approval.

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 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.

[i] A PMA applicant may request a Day 100 Meeting to discuss the review status of their PMA. FDA will inform the applicant of any identified deficiencies prior to the meeting, which will take place no later than 100 days after the receipt of the PMA application. Source: www.fda.gov, last consulted on 17 May 2024

[ii] The Pivotal Cohort is used for the primary effectiveness endpoints and consists of 40 patients implanted with the **alfa**pump

[iii] Data reported in press release of 25 October 2022

[iv] Data reported in press release of 19 October 2023

[v] Based on US and Canada market assessment conducted by highly experienced international consulting group