Sequana Medical announces FDA acceptance for substantive review of the Premarket Approval application for alfapump® in recurrent or refractory ascites due to liver cirrhosis

Acceptance and filing review is a first step in the PMA review process

Indicates PMA application is sufficiently complete for in-depth review

Received in advance of anticipated timing

Ghent, Belgium – 29 January 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 Premarket Approval (PMA) application for its **alfa**pump has been accepted for substantive review by the US Food and Drug Administration (FDA). 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 submitted with a filing date of 28 December 2023, and is now under substantive review by the FDA. This notification from the FDA was anticipated on 11 February 2024. Pending FDA approval, which the Company anticipates in the second half of 2024, **alfa**pump could become the first active implantable medical device in the US for treating liver ascites.

Timur Resch, Global Vice President QM/QA/RA at Sequana Medical, commented: *"The acceptance of our PMA file for substantive review by the FDA is an important milestone that reflects the tremendous efforts of our team. This achievement means that the FDA recognizes the completeness of our application and will now begin an in-depth review. We look forward to working closely with the FDA during the review process, with the ultimate goal of making the **alfa**pump available to US patients as soon as possible."*

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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[i] exceeded the predefined thresholds with statistical significance, and primary safety endpoint data was in line with expectations[ii]. 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[iii].

Data from the patient preference study and a matched cohort analysis of the NACSELD[iv] 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 6-7% per year, from 78,000 patients in 2025, reaching a market opportunity for **alfa**pump of over $2.5 billion by 2035, with NASH being the major driver of growth[v]. 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 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. MOJAVE, a US randomized controlled multi-center Phase 1/2a DSR clinical study is ongoing, with interim data expected in the second half of 2024. This study is seeking to confirm the strong efficacy seen in the RED DESERT and SAHARA studies. All three patients from the MOJAVE non-randomized cohort have been successfully treated with DSR and the DSMB approved the start of the randomized cohort of up to a further 30 patients

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 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.

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[i] The Pivotal Cohort is used for the primary effectiveness endpoints and consists of 40 patients implanted with the **alfa**pump
[ii] Data reported in press release of 25 October 2022
[iii] Data reported in press release of 19 October 2023
[iv] NACSELD is the North American Consortium for the Study of End Stage Liver Disease. A matched cohort analysis was conducted by an independent group comparing outcomes of decompensated cirrhosis patients from the NACSELD-III registry to those from the POSEIDON study; see press release of 19 October 2023
[v] Based on US and Canada market assessment conducted by highly experienced international consulting group, estimating over 170,000 patients with recurrent or refractory ascites in North America by 2035, with estimated incidence of 60% and based on $25K for price of **alfa**pump