1,000th alfapump® implant completed

- **Extensive real world alfapump experience derisks planned US & Canadian launch**
- **Strong clinical alfapump profile demonstrated in North American POSEIDON study**
- **All approvals received to commence US MOJAVE study of DSR 2.0**

Ghent, Belgium – 06 July 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 implanted the 1,000th **alfa**pump for the treatment of recurrent and refractory ascites due to liver cirrhosis and malignant ascites.

The Company also reports that it has received all administrative clearances to start the US MOJAVE study of DSR 2.0 in congestive heart failure patients and expects to enroll the first patient imminently.

Ian Crosbie, Chief Executive Officer of Sequana Medical, commented: *"We developed the **alfa**pump to transform the lives of patients with recurrent and refractory ascites due to liver disease. For too long they have had to rely upon large volume paracentesis, a therapy developed by the ancient Egyptians and with little improvement in the last two thousand years. This important patient population is forecast to grow strongly due to the increasing prevalence of NASH[i] / fatty liver disease, one of the key health challenges in North America today. We believe that the data recently presented at the EASL Liver meeting demonstrates the potential for **alfa**pump to transform patient lives – virtually eliminating needle paracentesis and delivering clinically important improvement in patient quality of life.*

*"We look forward to submit our Pre-Market Approval to the US FDA later this year and are preparing for commercial launch of the **alfa**pump in North America through our own specialty salesforce."*

A 63-year old alfapump patient from Canada said: *"The **alfa**pump changed my life. I thought I was going to die. I got lucky with the **alfa**pump, my daily routine is getting back, with no pain and suffering, just feeling good about taking care of myself. My approach to life totally changed since the **alfa**pump. I look at it as a second chance in life."*

<u>**alfa**pump – continuous ascites removal to the bladder</u>

Sequana Medical's **alfa**pump is a fully implantable, wirelessly charged device that continuously collects ascites as it forms in the abdominal cavity and moves it into the bladder, where it is naturally passed from the body through urination. Since the first **alfa**pump was implanted at the end of 2008, there has been a steady increase in the number of patients benefiting from the improved quality of life that the **alfa**pump brings. During that time, more than 100,000 liters of ascites have been removed safely with the **alfa**pump.

<u>Strong clinical **alfa**pump profile demonstrated in pivotal POSEIDON study</u>

Highlights from the Company's flagship POSEIDON study, which met all primary endpoints, were recently presented at the EASL Liver meeting in Vienna[ii]:

- **alfa**pump was effective in the control of ascites, virtually eliminating the need for large volume paracentesis

- Safety was in line with expectations, particularly given disease progression in these patients.
    - Six pumps were explanted: three due to skin erosion and three due to moderate bladder discomfort
    - Similar number of Major Adverse Events and comparable number of serious infections in pre- and post-implant period
    - Stable kidney function over long-term follow-up
- Clinically meaningful and statistically significant improvement in patients' quality of life at six months post-implantation
- One-year survival probability of 70%, comparing favorably to literature citing a survival rate of 50% at one year in this patient population.[iii]

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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 preparing to commence MOJAVE, a US randomized controlled multi-center Phase 1/2a clinical trial of DSR 2.0, with initial data expected in Q4 2023.

Sequana Medical is listed on Euronext Brussels (Ticker: SEQUA.BR) and headquartered in Ghent, Belgium. For further information, please visit http://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. 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] NASH: non-alcoholic steatohepatitis, also referred to as MASH (metabolic dysfunction-associated steatohepatitis) as per new fatty liver disease nomenclature (Hepatology, June 2023)
[ii] Reported in press release of 21 June 2023
[iii] Biggins et al., Hepatology, Vol. 74, No. 2, 2021, AASLD Practice Guidance; Moreau R et al., Liver International 2004: 24: 457-464