PRESS RELEASE
REGULATED INFORMATION – INSIDE INFORMATION
19 October 2023, 07:00 am CEST

Sequana Medical announces additional alfapump data supporting strong and durable clinical profile; PMA on track for year-end submission

- **One-year alfapump data from POSEIDON shows safety and strong efficacy profile is maintained at 12 months**
- **Patient preference study indicates that US patients have a strong preference for the alfapump vs large volume paracentesis[i]**
- **Matched interim analysis of patients from NACSELD[ii] registry and POSEIDON pivotal cohort indicates that alfapump safety profile is comparable to standard of care**
- **Positive pre-PMA[iii] meeting held with FDA to align on clinical data and benefit-risk analysis for the submission package**
- **On track for PMA submission by year end**

Conference call with live webcast by Sequana Medical today at 03:00 pm CEST / 09:00 am EST

Ghent, Belgium – 19 October 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 additional positive data supporting i) maintenance of **alfa**pump's safety and strong efficacy profile at 12 months, ii) safety in line with a matched cohort of patients from the NACSELD registry, and iii) strong preference amongst US patients for **alfa**pump versus standard of care, as well as completion of a positive meeting with the FDA to align on clinical data and benefit-risk analysis for the PMA submission package which is on track for year end.

Gijs Klarenbeek, Senior Medical Advisor of Sequana Medical, commented: *"These data are very positive and demonstrate that the **alfa**pump continues to transform the lives of patients with recurrent or refractory ascites at one year post-implantation, maintaining the virtual elimination of needle paracentesis and clinically meaningful improvement in quality of life. The comparison of POSEIDON patients to a matched cohort of subjects in the NACSELD registry is reassuring as it reaffirms **alfa**pump's safety profile."*

Ian Crosbie, Chief Executive Officer at Sequana Medical, added: *"We are delighted with these additional insights into **alfa**pump's long term benefit as well as the encouraging results from our patient preference study which indicates a strong preference amongst US patients for the **alfa**pump. We are greatly encouraged by our recent pre-PMA meeting with the FDA, where we discussed the reported clinical data from our **alfa**pump studies and benefit-risk analysis for the submission package. We look forward to submitting our PMA application by year end and continuing our preparations for launching the **alfa**pump in the US and Canada."*

One-year follow-up data from POSEIDON study

As seen in months 0-6 post implant, patients maintained the 100% median reduction in therapeutic paracentesis in the 7-12 month post-implant period vs the three month pre-implant period (n = 19). These data show that the **alfa**pump has a sustained effect on controlling ascites, virtually eliminating the need for therapeutic paracentesis.

During the 7-12 month post-implant period, two patients had the **alfa**pump explanted, one due to a urinary tract infection and one due to wound dehiscence and the number of Major Adverse Events (MAEs[iv]) and serious infections were in line with expectations. Importantly, creatine and eGFR[v] levels of **alfa**pump-treated patients over 12-month follow-up indicated a stable renal function. Overall, these safety data indicate that the **alfa**pump has a robust safety profile over long-term follow-up.

Quality of life, assessed through the physical component score of SF36 (a general health quality of life measure) and the Ascites Q score (a quality of life measure specific for patients with ascites), maintained a clinically meaningful improvement at 12 months post-implant vs three months pre-implant, despite disease progression.

The overall trend in survival[vi] in patients implanted with the **alfa**pump remained positive over a longer term, with a Kaplan-Meier estimate indicating over 70% survival probability at 12 and 18 months post-implant. This compares favourably with the published literature reporting a predicted survival probability for refractory ascites patients with a similar MELD[vii] score and receiving paracentesis of approximately 17% at 12 months and 5% at 18 months[viii].

Data from the POSEIDON study will be submitted for publication in a peer-reviewed journal. The Company will update the market as soon as it is published.

Outcome Patient Preference study

The patient preference study was conducted by RTI Health Solutions, thought leaders in the field. The rigorous study design was pre-discussed with the FDA and utilizes a discrete-choice experiment (DCE[ix]) methodology to elicit preferences of US patients with a physician-confirmed diagnosis of recurrent or refractory ascites due to liver cirrhosis for attributes of an implantable pump as a novel interventional treatment for ascites. Patients were surveyed for the risk of treatment-related adverse events they would be willing to accept (risk tolerance) to achieve specific improvements in treatment efficacy (desired benefits). In total, 125 US patients with a comparable patient profile as the Pivotal Cohort in the POSEIDON study, completed the survey.

Top-line results presented in the table below indicate that, on average, patients are willing to accept levels of risks greater than those observed in the POSEIDON study in exchange for improvements in treatment efficacy less than or equal to those observed in the POSEIDON study.

Risk tolerance (over 6 months)	Patient preference study Maximum acceptable risk	POSEIDON pivotal cohort Observed rate
Major surgery or death	>10%	0%
Minor procedure	>35%	20%
Serious infection or AKI resulting in hospitalization	>30%	20%

Desired benefits	Patient preference study	POSEIDON pivotal cohort
Reduction in frequency of paracentesis	100%	100% (median)
Additional ascites good health days each month	10	>10 (mean)

Reduction in paracentesis frequency and additional ascites good health days are important attributes for a novel interventional treatment for ascites. On average, patients responded with a 65% likelihood of selecting a treatment profile like the **alfa**pump vs regular paracentesis procedures and no implanted pump.

These data support the premise that **alfa**pump is a desirable treatment option for the majority of patients.

Matched interim analysis of NACSELD registry and POSEIDON pivotal cohort

The North American Consortium for the Study of End Stage Liver Disease (NACSELD) is a consortium of tertiary-care hepatology centers in North America formed to study patients with cirrhosis. NASCELD-III is an IRB[x] approved registry of outpatients with cirrhosis which was initiated in 2019 at ten centers in North America.

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. Forty decompensated ascites patients from NACSELD-III were matched to the forty patients from the Pivotal Cohort in the POSEIDON study, using baseline Ascites-Q score (reflecting burden of disease before **alfa**pump implantation) and sex. Patients were also comparable for age and baseline MELD score after matching.

Results for all cause hospitalization and death within six months were similar between the NACSELD-III registry matched patients and the POSEIDON pivotal cohort.

Six month data[xi]	NACSELD-III Registry Matched Patients	POSEIDON Pivotal Cohort[xii]
Any Death or Hospitalization	**55.0% (22/40)**	55.0% (22/40)
Death	**12.5% (5/40)**	12.5% (5/40)
Hospitalization	**42.5% (17/40)**	42.5% (17/40)
Median # of hospitalizations (min, max)	**1 (0, 5)**	1 (0, 4)
Liver Transplant	**7.5% (3/40)**	5.0% (2/40)

This analysis indicates that the safety profile of the **alfa**pump is in line with expectations and comparable to standard paracentesis procedures.

Data from the matched cohort analysis together with the positive data from the POSEIDON study indicate that patients implanted with the **alfa**pump benefit from significantly reduced number of paracentesis procedures and an improved quality of life without an increased risk of death or hospitalization compared to standard of care.

Details Conference Call and Webcast by Sequana Medical

Sequana Medical management will host a conference call with a live webcast presentation **today** at 03:00 pm CEST / 09:00 am EST.

- Registration webcast: please click here
- Registration conference call (only if you wish to participate in the Q&A): please click here. Once registered, you will receive dial-in numbers and a confirmation code.

The webcast and conference call will be conducted in English and a replay will be available on Sequana Medical's website shortly after.

For more information, please contact:

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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. 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 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. **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 has reported positive primary and secondary endpoint data from the North American pivotal POSEIDON trial of the **alfa**pump in recurrent or refractory ascites due to liver cirrhosis and is on track to file a Pre-Market Approval (PMA) application with the FDA by year end.

The Company has commenced MOJAVE, a US randomized controlled multi-center Phase 1/2a clinical trial of DSR 2.0 seeking to confirm the strong efficacy seen in the RED DESERT and SAHARA studies. The first two patients have been successfully treated with DSR 2.0, and top-line data from all of the first three patients is expected by year end. Sequana Medical recently reported that detailed biomarker analysis of RED DESERT and SAHARA patients indicates DSR's mechanism of action as breaking the vicious cycle of cardiorenal syndrome.

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] Large volume paracentesis is paracentesis of more than 5 liters (and part of standard of care)
[ii] NACSELD: North American Consortium for the Study of End stage Liver Disease
[iii] PMA: Pre-Market Approval
[iv] MAEs were pre-defined in the protocol together with the principal investigators and FDA as one of the following events: AKI > stage 2, hepatorenal syndrome, hepatic encephalopathy > grade 2, spontaneous bacterial peritonitis and reccurent or refractory infection related to paracentesis or the **alfa**pump system, procedure or therapy.
[v] eGFR: estimated Glomerular Filtration Rate, a measure of kidney function
[vi] POSEIDON study not powered for survival
[vii] MELD: Model for End-Stage Liver Disease scoring system based on laboratory parameters, and is used to predict three-month survival rate and consider patients for liver transplantation
[viii] Salerno et al., Gastroenterology 2007; 133:825-834; figure 2: estimated probability of death according to treatment allocation (TIPS or paracentesis) in hypothetical patients with different MELD scores
[ix] The DCE approach allows an analysis of individual stated preferences in response to hypothetical choices and enables the quantification of the relative importance of each attribute/level during the decision-making process.
[x] IRB: Institutional Review Board
[xi] Deaths and serious adverse events (SAE) requiring hospitalization are presented hierarchically such that if a subject died and experienced an SAE requiring hospitalization, they are counted under "Death"
[xii] POSEIDON data are derived from adverse event data during six months post-implant