

**Sequana Medical to host KOL event on  
“The challenge of diuretic resistance in the management of heart failure patients  
and the potential for alfapump® DSR therapy”**

***[Live webcast](#) with Dr. Jeffrey Testani on 11 December 2020 at 03:00 pm CET / 09:00 am EST***

**Ghent, BELGIUM – 07 December 2020 – Sequana Medical NV (Euronext Brussels: SEQUA)**, an innovator in the management of fluid overload in liver disease, malignant ascites and heart failure, today announces that it will hold a key opinion leader (KOL) event on the challenge of diuretic resistance in the management of heart failure patients and the potential for **alfapump®** DSR therapy, on Friday 11 December 2020 at 03:00 pm CET / 09:00 am EST.

The call will feature a presentation by KOL Jeffrey Testani, MD, MTR (Yale University School of Medicine), who will discuss the current treatment landscape and unmet medical need in treating patients with fluid overload due to heart failure, a major clinical problem and the leading cause of heart failure-related hospitalisations.

Fluid overload is responsible for 90% of the one million heart failure hospitalisations annually in the U.S. (over \$13 billion in direct costs). Diuretic-resistance is widespread – up to 40% of heart failure patients on IV loop diuretics have a poor response, and further evidenced by the 24% of patients re-admitted to hospital within 30 days of discharge. There is a high unmet need in these patients for a safe and effective treatment solution to treat fluid overload when diuretics are no longer effective, especially one that can be used in an out-patient chronic setting.

**alfapump** DSR (Direct Sodium Removal) is Sequana Medical’s breakthrough approach to fluid overload in heart failure. The system is fully implanted and offers the potential for significant clinical benefits as well as the improvement in quality of life for patients with diuretic-resistant heart failure. Clinical proof-of-concept was achieved in a first-in-human single dose DSR study and published in *[Circulation](#)*. Interim data from the first five patients in RED DESERT, the ongoing repeated dose study, indicated that **alfapump** DSR therapy was safe and effective at maintaining the sodium and fluid balance, replacing the need of diuretics. Moreover, **alfapump** DSR therapy restored diuretic response in these diuretic-resistant patients and the improvement was sustained for months post-treatment.

Dr. Jeffrey Testani and Sequana Medical’s management team will be available to answer questions following the formal presentations.

To register for the event, please click [here](#). The presentation and a replay of the webcast will be available on [Sequana Medical’s Investors website](#) shortly after the event.

**For more information, please contact:**

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### About Dr. Jeffrey Testani

Jeffrey Testani, MD, MTR is Associate Professor of Medicine and Director of Heart Failure Research at Yale University School of Medicine. Dr. Testani's primary research interest is the mechanistic understanding of cardiac-renal interactions, fluid and sodium homeostasis, and diuretic resistance in heart failure. His lab is funded by the National Institutes of Health and industry sources totalling over \$15 million, and is considered by many to be amongst the top laboratories in the world in this field of study. The lab utilizes techniques of translational research using prospective human clinical trials and large animal models to better understand mechanism and develop new therapies and diagnostics. Dr. Testani has over 100 peer-reviewed publications, with the key focus on understanding cardio-renal interactions in heart failure.

### About alfapump DSR (Direct Sodium Removal)

**alfapump** DSR is in clinical development as potential chronic therapy for patients with fluid overload due to heart failure. DSR therapy is a breakthrough approach that involves removing sodium from the body using diffusion via the peritoneal cavity with the use of a sodium-free solution known as DSR infusate. Once the sodium has been removed, the body eliminates excess fluid naturally through urination to restore the serum sodium concentration. Clinical proof-of-concept was achieved in a first-in-human single dose DSR study and published in [Circulation](#). Interim data from the first five patients in the ongoing repeated dose **alfapump** DSR study (RED DESERT) in diuretic-resistant heart failure indicated that **alfapump** DSR therapy was safe and effective at maintaining the sodium and fluid balance. No patients required loop diuretic therapy during the six-week **alfapump** DSR treatment. Following **alfapump** DSR treatment, loop diuretic responsiveness was restored to near normal levels and the effect was durable for months post-treatment with the majority of patients requiring little or no diuretic therapy.

### About Sequana Medical

Sequana Medical is a commercial stage medical device company developing the **alfapump** platform for the management of fluid overload in liver disease, malignant ascites and heart failure where diuretics are no longer effective. Fluid overload is a fast growing complication of advanced liver disease driven by NASH (non-alcoholic steatohepatitis) related cirrhosis and a common complication in heart failure. The U.S. market for the **alfapump** resulting from NASH-related cirrhosis is forecast to exceed €3 billion annually within the next 10-20 years. The heart failure market for the **alfapump** DSR (Direct Sodium Removal) is estimated to be over €5 billion annually in the U.S. and EU5 by 2026. Both indications leverage Sequana Medical's **alfapump**, a unique, fully implanted wireless device that automatically pumps fluid from the abdomen into the bladder, where it is naturally eliminated through urination.

In the U.S., the company's key growth market, the **alfapump** has been granted breakthrough device designation by the FDA for recurrent or refractory ascites due to liver cirrhosis. Interim data from the ongoing North American pivotal study (POSEIDON) showed positive outcomes against all primary endpoints of the study. This study is intended to support a future marketing application of the **alfapump** in the U.S. and Canada. In Europe, the **alfapump** is CE-marked for the management of refractory ascites due to liver cirrhosis and malignant ascites and is included in key clinical practice guidelines. Over 800 **alfapump** systems have been implanted to date. Building on its proven **alfapump** platform, Sequana Medical is developing the **alfapump** DSR, a breakthrough, proprietary approach to fluid overload due to heart failure. Clinical proof-of-concept was achieved in a first-in-human single dose DSR study and further supported by strong interim safety and efficacy results from the ongoing repeated dose **alfapump** DSR study (RED DESERT) in heart failure patients.

Sequana Medical is headquartered in Ghent, Belgium. For further information, please visit [www.sequanamedical.com](http://www.sequanamedical.com).

**Important Regulatory Disclaimers**

*The **alfapump**<sup>®</sup> system is not currently approved in the United States or Canada. In the United States and Canada, the **alfapump**<sup>®</sup> system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical study see [www.poseidonstudy.com](http://www.poseidonstudy.com). The 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. The DSR therapy is not currently approved for clinical research in the United States or Canada. There is no link between the DSR therapy and ongoing investigations with the **alfapump**<sup>®</sup> system in Europe, the United States or Canada.*

**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.*