

## Sequana Medical announces acceptance of late-breaking abstract of DSR therapy for volume overload in heart failure at Heart Failure 2019 Congress

**Ghent, BELGIUM – 30 April 2019 – Sequana Medical NV (Euronext Brussels: SEQUA)**, a commercial stage medical device company focused on the development of innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders, today announces that results from the first-in-human single dose DSR (Direct Sodium Removal) proof-of-concept study for volume overload in heart failure have been selected for oral presentation in the late-breaking abstract session at [Heart Failure 2019](#) on 27 May 2019. Heart Failure 2019 will be held from 25 to 28 May 2019 in Athens, Greece and is the 6<sup>th</sup> World Congress on Acute Heart Failure organised by the Heart Failure Association of the European Society of Cardiology.

*“First in Human Experience with Direct Sodium Removal using Zero Sodium Peritoneal Solution: A new candidate therapy for volume overload”* will be presented by Dr. Jeffrey Testani, Associate Professor at Yale University.

### Session Details:

Name: Late-breaking trial III – Innovative and device therapy

Date: Monday 27 May 2019

Time: 08:30 – 10:00 CEST

Presentation time: 09:30 CEST

Room: Trianti – lecture room (Megaron - Athens International Conference Centre)

Following the oral presentation, the abstract will be available on the website of Sequana Medical and the management team will host a conference call with a live webcast presentation on 27 May 2019 at 14:00 CEST.

### About the first-in-human single dose DSR proof-of-concept study

The study ([clinicaltrials.gov NCT03801226](https://clinicaltrials.gov/NCT03801226)) was conducted by Dr. Testani at Yale University, in up to 20 patients receiving peritoneal dialysis who underwent randomization and crossover to DSR infusate (a sodium-free solution) or standard peritoneal dialysis (PD) solution. One litre of either DSR infusate or standard PD solution was infused into the peritoneum and left to dwell for two hours before being removed. The patient repeated the procedure with the alternate solution one week later. The primary endpoints include safety and tolerability, defined as completion of the two-hour dwell without significant discomfort or adverse events. The secondary efficacy endpoint of the study is the difference in sodium removal between DSR infusate and standard PD solution.

### About DSR therapy

Sequana Medical’s proprietary DSR therapy is under development and is a novel approach to the management of volume overload in heart failure, a major clinical problem and a significant burden on healthcare systems. The body’s response to heart failure causes sodium levels to increase, which in turn leads to the body retaining more fluid. Sequana Medical’s innovative DSR therapy involves the removal of sodium via diffusion from the body into the peritoneal cavity by administering a sodium-free solution (“the DSR infusate”) into the abdomen. The DSR infusate and the extracted sodium are then removed, resulting in the elimination of sodium from the body. The body responds by eliminating the associated fluid via osmotic ultrafiltration (the movement of water, together with sodium, from the bloodstream to the peritoneal cavity) and/or urination.

The impact of administering a sodium-free solution to the peritoneal cavity, and the resulting sodium and fluid removal, was evaluated in a preclinical study with 15 pigs, of which five had experimentally induced heart

failure. The study demonstrated that DSR therapy is capable of removing large quantities of fluid and sodium whilst having a negligible impact on the sodium concentration in the bloodstream, indicating the potential of this therapeutic approach.

### **About Volume Overload in Heart Failure**

Volume overload in heart failure is a major clinical problem. There are an estimated 6.5 million adults in the U.S. suffering from heart failure and this number is expected to grow to 8.0 million by 2030. There are approximately one million hospitalisations for heart failure annually in the U.S. and 90% are due to symptoms of volume overload. The treatment options are severely limited in those patients for whom diuretic therapy is no longer effective. This limitation is evident from the 24% hospital re-admission rate at 30 days from discharge. The estimated cost of heart failure-related hospitalisations in the U.S. is \$13 billion per year.

### **About Sequana Medical**

Sequana Medical is a commercial stage medical device company focused on the development of innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders.

Sequana Medical's technology is based on its proprietary **alfapump**<sup>®</sup> platform, a fully implantable, programmable, wirelessly-charged, battery-powered system for automatic and continuous removal of fluid from the abdomen, which is applicable across multiple life-threatening disorders. The **alfapump** is being commercialised in Europe for the management of refractory ascites (chronic fluid build-up in the abdomen) due to liver cirrhosis and malignant ascites. The number of patients with refractory liver ascites is forecast to increase dramatically due to the growing prevalence of NASH (Non-alcoholic Steatohepatitis).

Over 700 **alfapump** systems have been implanted to date and since April 2018, the **alfapump** has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for decompensated cirrhosis. In January 2019, the FDA has granted Breakthrough Device designation for the **alfapump** for the treatment of recurrent or refractory liver ascites. The **alfapump** has not yet received regulatory approval in the U.S. and Canada and the Company expects to start POSEIDON, the North American pivotal study in the second half of 2019 to support approval of the **alfapump** in recurrent or refractory liver ascites.

The **alfapump** is one of the first safe and effective, long-term alternatives to large-volume paracentesis (LVP) for the management of ascites, offering major advantages to patients, clinicians and healthcare systems. By automatically and continuously moving ascites to the bladder, where the body eliminates it naturally through urination, the **alfapump** prevents fluid build-up and its possible complications, improving patient quality of life and nutrition, and potentially reducing hospital visits and healthcare costs. The **alfapump** DirectLink technology allows clinicians to receive pump performance information and more effectively manage patients treated by the **alfapump**.

Sequana Medical has leveraged its **alfapump** experience and is developing **alfapump** DSR to deliver a convenient and fully implanted system for DSR therapy, its novel and proprietary approach for the management of volume overload in heart failure. Data from animal studies presented at EuroPCR 2018 and HFSA 2018 indicate that DSR therapy is effective and safe. The first-in-human single dose DSR proof-of-concept study has been conducted by Dr. Testani at Yale University in the U.S. and results are scheduled to be presented at Heart Failure 2019 on 27 May 2019. The repeated dose DSR proof-of-concept study is expected to start in the second half of 2019.

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

**For more information, please contact:**

**Sequana Medical**

Lies Vanneste

Director IR

Tel: +32 (0) 498 05 35 79

Email: [IR@sequanamedical.com](mailto:IR@sequanamedical.com)

**Consilium Strategic Communications**

Amber Fennel, Alexandra Harrison, Marieke Vermeersch, Sukaina Virji

Tel: +44 (0) 203 709 5000

Email: [sequanamedical@consilium-comms.com](mailto:sequanamedical@consilium-comms.com)

***Important Regulatory Disclaimers***

*Any statement in this press release about safety and efficacy of the **alfapump** does not apply to the U.S. and Canada because the device is currently undergoing clinical investigation in these territories.*

*DSR therapy is still in development and it should be noted that any statements in this press release 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 **alfapump** system in Europe, the U.S. and 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.*