Press Release

Sequana Medical announces presentation of pre-clinical proof of concept results of its Direct Sodium Removal (DSR) therapy for the management of volume overload in heart failure at the Annual Scientific Meeting of the Heart Failure Society of America (HFSA)

DSR therapy demonstrated to be safe and effective in heart failure animal model

Zurich, SWITZERLAND – 17 September 2018 – Sequana Medical AG ("Sequana Medical"), 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, announces today positive findings from its Direct Sodium Removal ("DSR") therapy proof of concept study in pigs.

Sequana Medical's proprietary DSR therapy 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 DSR therapy involves the removal of sodium via diffusion from the peritoneal cavity by administering a sodium-free solution (the infusate) into the abdomen. The 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 and/or urination.

The impact of administering a sodium-free infusate to the peritoneal cavity, and the resulting sodium and fluid removal, was evaluated in a preclinical study with 20 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.

The findings of the study were presented by Principal Investigator Jeffrey Testani, MD MTR, Associate Professor, Yale University at the 22nd Annual Scientific Meeting of HFSA being held from 15-18 September in Nashville, Tennessee. The poster will be made available on the Sequana Medical website, under the news & events section.

Dr. Jeffrey Testani, Associate Professor at Yale University, commented: "Volume overload in heart failure is a major clinical challenge in the significant proportion of patients that no longer respond effectively to diuretic therapy. The concept of sodium and fluid removal via non-renal routes is an interesting approach given the limitations of existing therapies. These results show that by administering a relatively small volume of a sodium-free solution, DSR therapy can remove a clinically relevant amount of sodium and fluid."

Ian Crosbie, Chief Executive Officer of Sequana Medical, added: "Obtaining proof of concept in this preclinical study is an important step in the further development of DSR therapy and first in human studies are planned for later this year. Through leveraging our proven **alfa**pump® platform, we are developing the **alfa**pump® DSR system to deliver a convenient and fully implanted system for DSR therapy and intend to commence first in human studies with the system in the second half of 2019."

Contacts:

Sequana Medical AG
Lies Vanneste
Director IR
Tel: +32 (0) 498 05 35 79
Email: IR@sequanamedical.com

Consilium Strategic Communications
Amber Fennell, Alexandra Harrison, Sukaina Virji
Tel: +44 (0) 203 709 5000
Email: sequanamedical@consilium-comms.com

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Note to Editors

About Heart Failure

Volume overload in heart failure is a major clinical problem. There are 6.5 million adults in the U.S. suffering from heart failure and this number is forecasted to grow to 8.0 million by 2030. There are over one million hospitalisations in the United States (the "U.S.") each year due to heart failure 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 a 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 **alfa**pump® is a fully implantable, programmable, wirelessly-charged, battery-powered system that is CE-marked for the management of i) refractory ascites (chronic fluid build-up in the abdomen) due to liver cirrhosis and ii) malignant ascites (with a life expectancy of six months or less). The number of patients with liver refractory ascites is forecast to increase dramatically due to the growing prevalence of NASH (Non-alcoholic Steatohepatitis).

Over 650 **alfa**pump® systems have been implanted and since April 2018, the **alfa**pump® has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for decompensated cirrhosis. The **alfa**pump® MOSAIC North American IDE feasibility study in patients with liver refractory or recurrent ascites is complete and initial results were presented at the AASLD (American Association for the Study of Liver Diseases) in October 2017. The **alfa**pump® has not yet received a pre-market approval in the U.S.

The **alfa**pump® is one of the first safe and effective, long-term alternatives to large-volume paracentesis which is a lengthy, invasive and painful procedure, only providing short-term symptomatic relief, requiring hospital visits and placing a significant burden on the healthcare system and patient quality of life. By automatically and continuously moving ascites to the bladder, where the body eliminates it naturally through urination, the **alfa**pump® prevents fluid build-up and its possible complications, improving patient quality of life and nutrition, and potentially reducing hospital visits and healthcare costs. The **alfa**pump® DirectLink technology allows clinicians to receive pump performance information and more effectively manage patients treated by the **alfa**pump®.

Sequana Medical is developing the **alfa**pump® DSR, built upon the proven **alfa**pump® platform, to deliver a convenient and fully implanted system for DSR therapy, a novel and proprietary approach for the management of fluid overload in heart failure. Data from animal studies presented at EuroPCR 2018 and HFSA 2018 indicate that DSR therapy is effective and safe.

Sequana Medical is headquartered in Zurich, Switzerland and investors include NeoMed Management, Life Science Partners, VI Partners, BioMedPartners, Capricorn Venture Partners, Entrepreneur's Fund and Salus Partners. For further information, please visit www.sequanamedical.com.