## **Press Release**

# Sequana Medical reports positive data on use of the alfapump<sup>®</sup> in malignant ascites patients at the International Gynecologic Cancer Society

Data also to be presented at the 68th Annual Meeting of the Society of Pelvic Surgeons in Romania

**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 Retrospective Malignant Ascites Study.

The study retrospectively evaluated 17 patients with malignant ascites that had been implanted with the **alfa**pump<sup>®</sup> in centres across Europe. The study demonstrated that the **alfa**pump<sup>®</sup> was effective in treating palliative patients with malignant ascites and improving their quality of life.

The findings of the study were presented by Principal Investigator, Christina Fotopoulou MD, PhD, Imperial College London at the 17<sup>th</sup> Biennial Meeting of the International Gynecologic Cancer Society that was held from 14-16 September in Kyoto, Japan.

**Prof. Dr. Christina Fotopoulou at Imperial College London commented:** "The **alfa**pump<sup>®</sup> is a novel strategy offering a new opportunity for patients with refractory malignant ascites to have an improved quality of life and a lower need for hospitalisation, so that they can spend more time outside of a hospital environment. It is a very promising, minimally invasive technology that has the potential to significantly improve the quality of life of patients in a very difficult phase of their lives."

**Ian Crosbie, Chief Executive Officer of Sequana Medical, added:** "These data build upon our extensive clinical and commercial experience with the **alfa**pump<sup>®</sup> in liver refractory ascites and support our growth strategy in malignant ascites. Patients with malignant ascites have a poor prognosis where the impact of ascites on their quality of life is significant, often reducing their ability to withstand further cancer treatments. There is therefore a high unmet need for a therapy that manages malignant ascites and improves patients' quality of life. We believe that these data demonstrate the compelling potential of the **alfa**pump<sup>®</sup> to improve clinical outcomes for malignant ascites patients."

The data will also be presented at the 68<sup>th</sup> Annual Meeting of the Society of Pelvic Surgeons being held from 23-29 September 2018 in Bucharest, Romania.

#### Event details:

Date/Time presentation: Tuesday, 25 September 2018 at 11:15am local time Abstract title: Continuous low-flow ascites-drainage through the urinary bladder via the alfa-pump (AP) closed system in palliative patients with malignant ascites (MA)

The poster and presentation will be made available on Sequana Medical's website, under the <u>news &</u> <u>events section</u>, shortly after the event.

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## Note to Editors

#### **About Malignant Ascites**

Ascites is a common complication of certain late-stage cancers as a result of fluid accumulation in the peritoneal cavity due to a number of causes including draining of the lymph system. While life expectancy for many cancer patients with malignant ascites is short (less than 3 months), ovarian and breast cancer patients often have longer life expectancies.

As with ascites due to liver disease, paracentesis is used to eliminate the ascites that accumulates when diuretics are not effective. The impact of ascites on patient health reduces their ability to withstand anti-cancer therapies, thereby potentially reducing survival, and places a burden on the patient through a significant reduction in quality of life through regular hospital visits and impact on daily life.

There is a significant unmet medical need for a minimally invasive therapy to manage malignant ascites that does not cause a further detriment to quality of life among patients with an already poor prognosis. In addition to improving the quality of life for these patients, a long-term treatment for malignant ascites could enhance their ability to withstand additional cancer treatments and increase their chances of survival.

## 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<sup>®</sup> is a fully implantable, programmable, wirelessly-charged, batterypowered 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<sup>®</sup> systems have been implanted and since April 2018, the **alfa**pump<sup>®</sup> has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for decompensated cirrhosis. The **alfa**pump<sup>®</sup> 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<sup>®</sup> has not yet received a pre-market approval in the U.S.

The **alfa**pump<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> DirectLink technology allows clinicians to receive pump performance information and more effectively manage patients treated by the **alfa**pump<sup>®</sup>.

Sequana Medical is developing the **alfa**pump<sup>®</sup> DSR, built upon the proven **alfa**pump<sup>®</sup> platform, to deliver a convenient and fully implanted system for Direct Sodium Removal ("DSR") therapy, a 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. Treatment of volume overload in diuretic-resistant heart failure patients is a major clinical challenge. There are an estimated one million hospitalisations due to heart failure in the United States (the "U.S.") each year, of which 90% are due to symptoms of volume overload. The estimated cost of heart failure-related hospitalisations in the U.S. is \$13 billion.

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 <u>www.sequanamedical.com</u>.