### **Press Release**

# Sequana Medical Announces Publication of Results of alfapump<sup>®</sup> Multicentre, Post-Marketing Surveillance Registry in Alimentary Pharmacology & Therapeutics (AP&T).

Zurich, SWITZERLAND 4 October 2017 -- Sequana Medical AG (Sequana Medical), a commercial stage medical device company and an innovator in the management of liver disease, announces the publication of "Treatment of refractory ascites with an automated low-flow ascites pump in patients with cirrhosis", the results of the first 56 patients in the **alfa**pump<sup>®</sup> multicentre Post-Marketing Surveillance Registry (PMSR) in AP&T (Alimentary Pharmacology & Therapeutics) (http://onlinelibrary.wiley.com/doi/10.1111/apt.14331/epdf).

In the largest reported series to-date of patients implanted with the **alfa**pump<sup>®</sup>, the continuous drainage of ascites with the **alfa**pump<sup>®</sup> led to a significant reduction in paracentesis frequency, with the median frequency of paracentesis dropped over 90%, from 2.17 to 0.17 per month.

Fifty-six **alfa**pump<sup>®</sup> patients (43 males, 13 women; mean age 62 years) with a contraindication to TIPSS (transjugular intrahepatic portosystemic shunt), from centres in Germany, Switzerland, UK and Spain were followed for up to 24 months. Complications, device deficiencies, paracentesis frequency and patient survival were recorded.

Dr. Guido Stirnimann of University Hospital Inselspital Bern, Switzerland, lead author of the manuscript, commented "The management of refractory ascites in patients with cirrhosis is challenging and novel therapies are an unmet need in Hepatology, due to the important limitations of both large volume paracentesis and TIPSS. The results of this largest reported series to-date of **alfa**pump<sup>®</sup> patients, demonstrates that in real life subjects **alfa**pump<sup>®</sup> provides an innovative and effective treatment option."

"We are very pleased the results from the post-marketing surveillance registry has clearly demonstrated that the **alfa**pump<sup>®</sup> delivers important benefits with this key complication of liver disease" said Ian Crosbie, Chief Executive Officer of Sequana Medical. "Through our ongoing development work and close collaboration with clinicians, we continue to further improve the performance of the **alfa**pump<sup>®</sup>. We are already seeing the impact of this in our more recent patient implants where we are seeing much lower rates of adverse events and reinterventions, and even greater reductions in paracentesis frequency."

## About Refractory Ascites (RA)

Accumulation of ascites is a common complication of cirrhosis and one of the leading reasons for hospital admission. The number of patients with cirrhosis is predicted to grow significantly, with much of the growth due to the increasing prevalence of non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH).

Approximately 60% of cirrhotic patients develop ascites within 10 years of diagnosis. An estimated 10% of patients with ascites develop refractory ascites, where the ascites cannot be treated with diuretics and restriction of dietary sodium. The most frequent treatment for RA patients is paracentesis, a lengthy, invasive and painful procedure that can require weekly hospital visits for drainage of excess fluid and is associated with poor quality-of-life. This often involves the drainage of over 5 litres of fluid and is termed large volume paracentesis.

## About the alfapump®

Sequana Medical's **alfa**pump<sup>®</sup> is a fully implantable, programmable, transcutaneously-charged, batterypowered pump for the management of refractory ascites. By moving ascites to the bladder, the body can eliminate 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>.

Over 600 **alfa**pump<sup>®</sup> systems have been implanted and the product is currently commercially available in Europe.

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### Note to Editors

#### About Sequana Medical:

Sequana Medical is a commercial stage medical device company and an innovator in the management of liver disease.

The first product, **alfa**pump<sup>®</sup>, is a fully implantable, programmable, transcutaneously-charged, batterypowered pump for the management of refractory ascites (chronic fluid build-up in the abdomen) due to i) liver cirrhosis, or ii) malignant ascites with a life expectancy of 6 months or less. The **alfa**pump<sup>®</sup> is one of the first real alternatives to large-volume paracentesis, a lengthy, invasive and painful procedure that can require weekly hospital visits for drainage of excess fluid. By moving ascites to the bladder, where the body can eliminate 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>. The **alfa**pump<sup>®</sup> has received the CE Mark and is commercially available in 14 countries. The **alfa**pump<sup>®</sup> is currently under evaluation in the US under an IDE study.

Through the experience gained from the design, development, manufacture and commercialisation of the **alfa**pump<sup>®</sup>, together with an extensive intellectual property portfolio, Sequana Medical has established an enabling platform for fully implantable fluid-imbalance therapies.

The Company is headquartered in Zurich, Switzerland and our investors include NeoMed Management, VI Partners, Biomed Invest, Capricorn Health Tech, Entrepreneur's Fund, Quest for Growth, Salus Partners and Life Science Partners. For further information, please visit <u>www.sequanamedical.com</u>.