

Press Release

Sequana Medical Announces Publication of Results of Multicentre Randomized Controlled Study: Patients with refractory ascites treated with **alfapump® system have better health-related quality of life as compared to those treated with large volume paracentesis**

Zurich, SWITZERLAND – 19. March 2018 -- Sequana Medical AG (“Sequana Medical”), a commercial stage medical device company and an innovator in the management of liver disease, announces the publication of a multicentre, randomized controlled study in Quality of Life Research (<https://link.springer.com/journal/11136>).

The study demonstrated that patients with refractory ascites treated with **alfapump**® system have better health-related quality of life as compared to those treated with large volume paracentesis.

In this multicentre, open-label randomized controlled trial, subjects were randomised to receive the **alfapump**® (AP) or large volume Paracentesis (LVP) (27 AP, 31 SoC). The SF-36v2 and CLDQ scores were compared between the two treatment arms at screening and monthly during treatment.

At baseline, no differences were seen between the treatment arms (all $p > 0.05$): age 61.9 ± 8.4 , 79.3% male, MELD scores 11.7 ± 3.3 , 85.2% Child–Pugh class B, 70.7% had alcoholic cirrhosis. The mean number of LVP events/subject was lower in **alfapump**® than LVP (1.1 vs. 8.6, in 6 months after treatment; $p < 0.001$). The health-related quality of life (HRQL) scores showed a moderate improvement from the baseline levels in subjects treated with **alfapump**® ($p < 0.05$ for abdominal and activity scores of CLDQ) but not with LVP (all one-sided $p > 0.05$) in the first 3 months. Subjects with refractory ascites who were treated with LVP continued to worsen their HRQL and experience no HRQL benefit. In contrast, subjects with refractory ascites who were treated with **alfapump**® system did experience improvement of HRQL as early as 1 month after treatment initiation. In fact, this improvement continued with longer follow-up of those subjects, and clinically meaningful HRQL superiority was noted in multiple domains related to bodily pain, other systemic symptoms, and fatigue. It is also important to note that the superiority of HRQL in patients treated with **alfapump**® remained significant even after controlling for other known predictors of HRQL scores. This supports HRQL-related benefits of **alfapump**® system over LVP.

Conclusion

As compared to LVP, the use of **alfapump**® system is associated with both a reduction in the number of LVP events and improvement of health-related quality of life.

“These results are very encouraging”, commented Professor Rajiv Jalan, Professor of Hepatology at the UCL Medical School, and investigator of the **alfapump**® randomized controlled trial. “Refractory ascites has a marked impact on these patient’s quality of life and the **alfapump**® demonstrated it provides a clinically meaningful improvement of HRQL. This benefit is of particular importance as a poor physical component of QoL in patients with refractory ascites is associated with increased mortality”.

“We are very pleased that these results clearly demonstrate that the **alfapump**® delivers better health-related quality of life to refractory ascites patients as compared to those treated with large volume paracentesis” said Ian Crosbie, Chief Executive Officer of Sequana Medical. “Improving the health-related quality of life is one of the key clinical objectives in the management of these patients. We believe that this benefit combined with the significant reduction in the number of LVP / subject demonstrates that the **alfapump**® is an important treatment option for the treatment of refractory ascites - a market that is forecast to grow significantly due to NAFLD and NASH.”

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, and therefore ascites 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 or 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 **alfapump**[®] is a fully implantable, programmable, transcutaneously-charged, battery-powered pump for the management of refractory ascites. By moving ascites to the bladder, the body can eliminate 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**[®].

Over 600 **alfapump**[®] 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 & malignant ascites, and is developing products for the management of heart failure and other fluid imbalance disorders.

The first product, **alfapump**[®], is a fully implantable, programmable, transcutaneously-charged, battery-powered pump for the management of refractory ascites (chronic fluid build-up in the abdomen) due to liver cirrhosis or malignant ascites with a life expectancy of 6 months or less. The **alfapump**[®] 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 **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**[®]. The **alfapump**[®] has received the CE Mark and is commercially available Europe. The **alfapump**[®] is currently under evaluation in the US under an IDE study, and the interim results of the MOSAIC study were presented at the AASLD in October 2017.

Through the experience gained from the design, development, manufacture and commercialisation of the **alfapump**[®], together with an extensive intellectual property portfolio, Sequana Medical has established an enabling platform for the management of heart failure and other fluid-imbalance disorders.

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