sequanamedical

Sequana Medical announces that the results of the alfapump® MOSAIC study have been published in *Liver Transplantation*

North American feasibility study demonstrated the utility, safety and efficacy of the alfapump in the management of patients with recurrent and refractory ascites

Ghent, BELGIUM – 16 June 2020 – Sequana Medical NV (Euronext Brussels: SEQUA), an innovator in the management of fluid overload in liver disease, malignant ascites and heart failure, today announces that the results of MOSAIC, the North American feasibility study of the **alfa**pump in recurrent and refractory liver ascites, have been published in *Liver Transplantation*, the peer-reviewed publication of the American Association for the Study of Liver Diseases.

The publication entitled "Improvement in Quality of Life and Decrease in Large-Volume Paracentesis Requirements with the Automated Low-Flow Ascites Pump" concluded that the **alfa**pump appears to be a promising treatment for refractory ascites in cirrhosis, especially in patients who are not TIPS candidates.

Prof. Florence Wong, investigator of the MOSAIC study and lead author of the *Liver Transplantation* article, said: "We are glad to have the opportunity to present the results of MOSAIC in this respected peer-reviewed journal. We found that the **alfa**pump system is a feasible treatment for recurrent ascites in patients with cirrhosis who are not suitable for TIPS insertion, especially in those with relatively preserved liver function, and has the potential to improve their day-to-day lives."

Ian Crosbie, CEO of Sequana Medical, added: "The publication of the MOSAIC data in this peer-reviewed journal further supports use of our **alfa**pump and its potential to address major and urgent unmet medical needs in liver cirrhosis. The designation of Breakthrough Device status by the FDA and the forecast growth in liver cirrhosis due to NASH makes the need for improved treatment options all the more important. The pivotal North American POSEIDON study, intended to support a commercial marketing application of the **alfa**pump in the U.S. and Canada, is underway and we look forward to making our innovative **alfa**pump available for patients suffering from this severe and underserved medical condition."

For more information, please contact:

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

Consilium Strategic Communications
Amber Fennell, Ashley Tapp, Melissa Gardiner
Tel: +44 203 709 5000
Email: sequanamedical@consilium-comms.com

LifeSci Advisors
Chris Maggos
Tel: +41 79 367 6254
Email: chris@lifesciadvisors.com

About the MOSAIC feasibility study

MOSAIC is a prospective, open-label, single-arm, multi-centre study comprising 30 cirrhotic patients with recurrent or refractory ascites not eligible for transjugular intrahepatic portosystemic shunt (TIPS). This North American feasibility study demonstrated that the **alfa**pump dramatically reduced the mean large-volume paracentesis (LVP) frequency per patient per month from 2.4 (±1.4) to 0.2 (±0.4). Implantation with the

alfapump also resulted in a clinically significant improvement in patients' quality of life and a better biochemical index of their nutritional status.

About the POSEIDON pivotal study

POSEIDON is a single-arm, open-label study and is expected to include up to 50 patients to be implanted with the **alfa**pump in approximately 20 centres across the U.S. and Canada for primary endpoint analysis. The primary effectiveness outcome of the study will include the proportion of patients with a 50% reduction in overall average frequency of paracentesis per month post-implantation versus pre-implantation. This endpoint will be evaluated at nine months after enrolment. Patients will be followed for up to two years after implantation for analysis of secondary outcome measurements. First patients were enrolled in the study in H2 2019. For more information about the study, please visit clinicaltrials.gov (NCT03973866).

About Sequana Medical

Sequana Medical is a commercial stage medical device company developing the **alfa**pump platform for the management of fluid overload in liver disease, malignant ascites and heart failure. Fluid overload is a fast growing complication of advanced liver disease driven by NASH (non-alcoholic steatohepatitis) related cirrhosis and a common complication in heart failure. The U.S. market for the **alfa**pump resulting from NASH-related cirrhosis is forecast to exceed €3 billion annually within the next 10-20 years. The heart failure market for the **alfa**pump DSR (Direct Sodium Removal) is estimated to be over €5 billion annually in the U.S. and EU5 by 2026. Both indications leverage Sequana Medical's **alfa**pump, a unique, fully implanted wireless device that automatically pumps fluid from the abdomen into the bladder, where it is naturally eliminated through urination.

In the U.S., the company's key growth market, the **alfa**pump has been granted breakthrough device designation by the FDA. The North American pivotal study (POSEIDON) in recurrent and refractory ascites due to liver cirrhosis is currently underway, and is intended to support a commercial marketing application of the **alfa**pump in the U.S. and Canada. In Europe, the **alfa**pump is CE-marked for the management of refractory ascites due to liver cirrhosis and malignant ascites and is included in key clinical practice guidelines. Over 750 **alfa**pump systems have been implanted to date. Building on its proven **alfa**pump platform, Sequana Medical is developing **alfa**pump DSR, a breakthrough, proprietary approach to fluid overload due to heart failure. Clinical proof-of-concept was achieved in a first-in-human single dose DSR study and a repeated dose **alfa**pump DSR study (RED DESERT) in heart failure patients is currently underway.

Sequana Medical is headquartered in Ghent, Belgium. For further information, please visit www.sequanamedical.com.

Important Regulatory Disclaimers

*The **alfa**pump has not yet received regulatory approval in the U.S. and Canada. Any statement in this press release about safety and efficacy of the **alfa**pump does not apply to the U.S. and Canada because the device is currently undergoing clinical investigation in these territories.*

*DSR therapy and **alfa**pump DSR are still in development and it should be noted that any statements in this press release regarding safety and efficacy arise from pre-clinical studies and ongoing clinical investigations which have yet to be completed. There is no link between DSR therapy, **alfa**pump DSR and ongoing investigations with the **alfa**pump 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.