PRESS RELEASE

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Sequana Medical announces inclusion of alfapump® in German treatment guidelines (DGVS) for complications of liver cirrhosis

Further validation builds on U.S. FDA[1] Breakthrough Device status and inclusion in U.K. NICE[2] recommendations and EASL[3] guidelines

Ghent, BELGIUM – 15 May 2019 – Sequana Medical NV (Euronext Brussels: SEQUA), 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, today announces that the **alfa**pump has been included in the DGVS ("German Society of Gastroenterology Digestive and Metabolic Diseases") guidelines for complications of liver cirrhosis. These guidelines provide evidence-based key recommendations for diagnosis and therapy of complications of liver cirrhosis and upgrade the 2011 version. An interdisciplinary team of medical experts and patient support groups developed the guidelines following the recommendations by the Association of Scientific Medical Societies for evidence-based consensus guidelines.

Sequana Medical's **alfa**pump is currently commercialised in Europe for the treatment of refractory liver ascites, which is a key complication of liver cirrhosis with limited treatment options and severely impacting patients' quality of life. The potential of the **alfa**pump to address this unmet medical need has been demonstrated in multiple clinical studies showing a significant reduction in the need for large volume paracentesis (LVP), the current standard of care, and a significant improvement in patients' quality of life.

The DGVS guidelines position the **alfa**pump as a good and safe alternative to repeated LVP and states that the **alfa**pump may also be considered in patients contraindicated for use of a transjugular intrahepatic portosystemic shunt (TIPS). There are numerous complications with TIPS, including hepatic encephalopathy and heart failure. Reference is made to the improvement in clinical outcomes through extensive clinical experience with the **alfa**pump, as well as to the improvement in patient's quality of life and nutritional benefit demonstrated in clinical studies.

Prof. Dr. Thomas Berg, Head of Hepatology at the University of Leipzig, commented: "I welcome the inclusion of the **alfa**pump in the DGVS guidelines which are considered the reference treatment guidelines in Germany for patients suffering from complications of liver cirrhosis. There is a clear need for treatment alternatives for this underserved patient group. The increasing body of clinical evidence and real-world experience demonstrate the benefits of using the **alfa**pump when performed in experienced centres and well-selected patients with refractory liver ascites."

Ian Crosbie, Chief Executive Officer at Sequana Medical, added: "The inclusion of the **alfa**pump in the DGVS guidelines is further proof of the increasing independent support and acceptance for **alfa**pump use. We look forward to starting our North American POSEIDON pivotal study in recurrent or refractory liver ascites, expected in the second half of 2019, to support approval of the **alfa**pump in the U.S. and Canada. The forecast

[1] Food and Drug Administration
[2] The National Institute for Health and Care Excellence
[3] European Association for the Study of the Liver

growth in cirrhosis and refractory ascites as a result of non-alcoholic steatohepatitis (NASH) is a key health concern in the U.S. and makes the need for a modern and convenient treatment option all the more important."

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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 technology is based on its proprietary **alfa**pump® platform, a fully implantable, programmable, wirelessly-charged, battery-powered system for automatic and continuous removal of fluid from the abdomen, which is applicable across multiple life-threatening disorders. The **alfa**pump is being commercialised in Europe for the management of refractory ascites (chronic fluid build-up in the abdomen) due to liver cirrhosis and malignant ascites. The number of patients with refractory liver ascites is forecast to increase dramatically due to the growing prevalence of NASH (Non-alcoholic Steatohepatitis).

Over 700 **alfa**pump systems have been implanted to date 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. In January 2019, the FDA has granted Breakthrough Device designation for the **alfa**pump for the treatment of recurrent or refractory liver ascites. The **alfa**pump has not yet received regulatory approval in the U.S. and Canada and the Company expects to start POSEIDON, the North American pivotal study in in the second half of 2019 to support approval of the **alfa**pump in recurrent or refractory liver ascites.

The **alfa**pump is one of the first safe and effective, long-term alternatives to large-volume paracentesis (LVP) for the management of ascites, offering major advantages to patients, clinicians and healthcare systems. 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 has leveraged its **alfa**pump experience and is developing **alfa**pump DSR to deliver a convenient and fully implanted system for DSR therapy, its 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. The first-in-human single dose DSR proof-of-concept study has been conducted by Dr. Testani at Yale University in the U.S. and results are scheduled to be presented

at Heart Failure 2019 on 27 May 2019. The repeated dose DSR proof-of-concept study is expected to start in the second half of 2019.

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

Important Regulatory Disclaimers

*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 is 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 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.