Sequana Medical announces granting of key alfapump DSR® patents in U.S. and Europe

Ghent, BELGIUM – 4 February 2021 – Sequana Medical NV (Euronext Brussels: SEQUA), an innovator in the treatment of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure, today announces the granting of key patents for the **alfa**pump DSR (Direct Sodium Removal) programme in the U.S. and European Union.

U.S. patent number 10,898,631 B2 and EU patent number EP 3 612 246 B1 are both entitled "*Direct sodium removal method, solution and apparatus to reduce fluid overload in heart failure patients*" and cover the **alfa**pump DSR and its method of operation. Specifically, it covers the use of a no or low sodium infusate that is administered to a patient's peritoneal cavity to directly remove sodium, and thereby fluid from the body to alleviate fluid overload in heart failure patients with residual renal function.

Ian Crosbie, Chief Executive Officer at Sequana Medical, commented: "We are very pleased with the granting of these patents in our key territories, which we believe provides significant protection for our **alfa**pump DSR programme. We are excited for the prospect of this breakthrough approach to the potential treatment of diuretic-resistant fluid overload in heart failure – an enormous burden on patients, clinicians and payers. The strong interim results from the RED DESERT study that we announced in October 2020 suggest that not only can **alfa**pump DSR therapy potentially manage the fluid and sodium balance of these patients without the need of diuretics but also restore their diuretic responsiveness, enabling a gentler and more effective management of this enormous problem. Following these very promising data, we intend to explore the use of **alfa**pump DSR therapy in fluid overload related to haemodialysis and pre-dialysis renal failure. We look forward to reporting the top-line data from the RED DESERT study in up to 10 patients by the end of H1 2021 and initiating SAHARA DESERT, our dose-ranging study of **alfa**pump DSR in decompensated heart failure patients."

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About alfapump **DSR®**

alfapump DSR is in clinical development as potential chronic therapy for patients with fluid overload due to heart failure. DSR® therapy is a unique approach that works in partnership with the body. It involves removing sodium from the body using diffusion via the peritoneal cavity with the use of a sodium-free solution known as DSR infusate. Once the sodium has been removed, the body eliminates excess fluid naturally through urination to restore the serum sodium concentration. Clinical proof-of-concept was achieved in a first-in-human single dose DSR study and published in *Circulation*. Interim data from the first five patients in the ongoing repeated dose **alfa**pump DSR study (RED DESERT) in diuretic-resistant heart failure indicated that **alfa**pump DSR therapy was safe and effective at maintaining the sodium and fluid balance. No patients required loop diuretic therapy

during the six-week **alfa**pump DSR treatment. Following **alfa**pump DSR treatment, loop diuretic responsiveness was restored to near normal levels and the effect was durable for months post-treatment with the majority of patients requiring little or no diuretic therapy.

About Sequana Medical

Sequana Medical is a commercial stage medical device company developing the **alfa**pump® platform for the treatment of fluid overload in liver disease, malignant ascites and heart failure where diuretics are no longer effective. 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 with diuretic resistance being widespread in both of these indications. 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 for recurrent or refractory ascites due to liver cirrhosis. Interim data from the ongoing North American pivotal study (POSEIDON) showed positive outcomes against all primary endpoints of the study. This study is intended to support a future 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 800 **alfa**pump systems have been implanted to date. Building on its proven **alfa**pump platform, Sequana Medical is developing the **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 further supported by strong interim safety and efficacy results from the ongoing repeated dose **alfa**pump DSR study (RED DESERT) in heart failure patients.

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

Important Regulatory Disclaimers

*The **alfa**pump® system is not currently approved in the United States or Canada. In the United States and Canada, the **alfa**pump system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical study see www.poseidonstudy.com. The DSR® therapy is still in development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. The DSR therapy is not currently approved for clinical research in the United States or Canada. There is no link between the DSR therapy and ongoing investigations with the **alfa**pump system in Europe, the United States or 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.

***Note: alfa**pump® is a registered trademark. DSR® and **alfa**pump DSR® are registered trademarks in the Benelux.*