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An investment in the offered shares involves substantial risks and uncertainties. Prospective investors should read the entire Prospectus that will be prepared by the Company, and, in particular, should see the section "Risk Factors" of the Prospectus for a discussion of certain factors that should be considered in connection with an investment in the offered shares. The risk factors that will be described in the Prospectus will include the risks that Sequana Medical has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability, that Sequana Medical's future financial performance will depend on the commercial acceptance of the alfapump® (Sequana Medical's only commercial-stage product to date), the alfapump® DSR and/or any future products in target markets, that Sequana Medical will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit Sequana Medical's access to additional capital, and that, not taking into account any proceeds of the Offering, Sequana Medical does not have sufficient working capital to meet its working capital needs for a period of at least 12 months from the date of the Prospectus. All of these factors should be considered before investing in the offered shares. Prospective investors must be able to bear the economic risk of an investment in the offered shares and should be able to sustain a partial or total loss of their investment.

sequanamedical

Press Release

Sequana Medical receives Breakthrough Device designation from the FDA for its alfapump®

Administrative process for the move of its business from Switzerland to Belgium completed

Ghent, BELGIUM – 29 January 2019 – Sequana Medical NV ("Sequana Medical", the "Company"), 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, announces today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation for the **alfapump®** for the treatment of liver recurrent or refractory ascites.

The FDA's Breakthrough Devices Program is designed to facilitate the development and expedite the review of devices that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and to provide patients and healthcare providers with timely access to these medical devices. Devices that receive this designation are eligible for more frequent interactions with the FDA's experts to identify areas of agreement in a timely way and are eligible for prioritized review of the submission package to obtain regulatory approval in the U.S.

Ascites, a key complication of liver cirrhosis, is the accumulation of ascitic fluid in the abdomen. Patients may accumulate as much as 10 to 15 litres of ascitic fluid within the abdomen every 15 days. Patients suffering from liver recurrent or refractory ascites have limited treatment options and often have severely impacted quality of life due to the severe swelling of the abdomen, resulting in pain, difficulty breathing, moving, sleeping and eating, severe nausea and constipation. Existing treatment options carry the risk of significant or life-threatening side effects, provide only short-term symptomatic relief or have very limited availability.

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The **alfapump**[®] is a fully-implanted, programmable, wireless, CE-marked system that automatically pumps ascites from the peritoneal cavity into the bladder, where the body eliminates the ascites naturally through urination. The potential of the **alfapump**[®] to address this unmet medical need in patients with liver recurrent or refractory ascites has been demonstrated in multiple clinical studies showing a significant reduction in the need for large volume paracentesis, which is paracentesis where at least 5 litres of fluid is removed (i.e., the current standard of care), and a significant improvement in patients' quality of life.

A feasibility study in North America in patients with liver refractory or recurrent ascites has been completed and results were presented at the AASLD (American Association for the Study of Liver Diseases) annual meetings in October 2017 and November 2018. Preparations are underway to start a North American pivotal study in the second half of this year for approval of the **alfapump**[®] in North America.

Dr Patrick S. Kamath, Professor of Medicine at the Mayo Clinic, College of Medicine and Science Rochester MN commented:

"This is encouraging news for patients and their families. Patients suffering from recurrent or refractory ascites currently have limited treatment options. Ascites significantly reduces quality of life and requires frequent visits to a medical facility for treatment. The **alfapump**[®] treats ascites at home without the risk of hepatic encephalopathy and is associated with improved quality of life. The designation of FDA Breakthrough Device status for the **alfapump**[®] could make a much needed effective treatment of refractory or recurrent ascites available sooner for doctors and their patients."

Ian Crosbie, Chief Executive Officer at Sequana Medical, added:

"The designation of Breakthrough Device status by the FDA is a recognition both of the high unmet medical need in patients with recurrent or refractory ascites and the potential for the **alfapump**[®] to improve the lives of these patients. The forecast growth in liver cirrhosis resulting from NASH makes the need for improved treatments all the more important. We look forward to continuing to work with the FDA to expedite the development process and bring the **alfapump**[®] to U.S. patients as quickly as possible."

Update regarding the status of the Initial Public Offering on Euronext Brussels:

The administrative process for the move of Sequana Medical's business from Switzerland to Belgium has been completed. Meanwhile, the IPO preparations continue being progressed according to plan, and the Company will provide a further update on the IPO process in due course.

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Note to Editors

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 **alfapump**[®] is a fully implantable, programmable, wirelessly-charged, battery-powered system that is CE-marked for the management of i) refractory ascites (chronic fluid build-up in the abdomen) due to liver cirrhosis and ii) malignant ascites (with a life expectancy of six months or less). The number of patients with liver refractory ascites is forecast to increase dramatically due to the growing prevalence of NASH (Non-alcoholic Steatohepatitis).

Over 650 **alfapump**[®] systems have been implanted and since April 2018, the **alfapump**[®] has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for decompensated cirrhosis. The **alfapump**[®] MOSAIC North American IDE feasibility study in patients with liver refractory or recurrent ascites has been completed and results were presented at the AASLD (American Association for the Study of Liver Diseases) annual meetings in October 2017 and November 2018. The **alfapump**[®] has not yet received regulatory approval in the United States (the "U.S.").

The **alfapump**[®] is one of the first safe and effective, long-term alternatives to large-volume paracentesis which is a lengthy, invasive and painful procedure, only providing short-term symptomatic relief, requiring hospital visits and placing a significant burden on the healthcare system and patient quality of life. By automatically and continuously moving ascites to the bladder, where the body eliminates 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**[®].

Sequana Medical is developing the **alfapump**[®] DSR, built upon the proven **alfapump**[®] platform, to deliver a convenient and fully implanted system for Direct Sodium Removal ("DSR") therapy, a 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. A first-in-human study for DSR therapy is ongoing. Treatment of volume overload in diuretic-resistant

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heart failure patients is a major clinical challenge. There are an estimated one million hospitalisations due to heart failure in the U.S. each year, of which 90% are due to symptoms of volume overload. The estimated cost of heart failure-related hospitalisations in the U.S. is \$13 billion a year.

Sequana Medical is headquartered in Ghent, Belgium and investors include NeoMed Management, LSP (Life Science Partners), VI Partners, BioMedPartners, Capricorn Venture Partners, Entrepreneur's Fund, Salus Partners, Newton Biocapital, PMV and SFPI-FPIM. For further information, please visit www.sequanamedical.com.

Important Regulatory Disclaimer

Any statement in this press release about safety and efficacy of the **alfapump**[®] does not apply to the U.S. and Canada because the device is currently undergoing clinical investigation in these territories.

Important Information

This announcement does not constitute, or form part of, an offer or invitation to sell or issue, or any solicitation of an offer to purchase or subscribe for shares of Sequana Medical NV (the "Company"). Any purchase of, subscription for or application for, shares in the Company to be issued in connection with the intended offering should only be made on the basis of information contained in the prospectus in connection with the intended offering and any supplements thereto, as the case may be (the "Prospectus"). When the Prospectus is published (as the case may be), it will (inter alia) be made available to prospective investors at no cost at the Company's registered office. Subject to country restrictions, the Prospectus will also be available to prospective investors on the following website: www.sequanamedical.com.

This announcement is not a prospectus. The information contained in this announcement is for informational purposes only and does not purport to be full or complete. Investors should not subscribe for any securities referred to in this document except on the basis of information contained in the Prospectus that the Company expects to publish after its approval by the Belgian Financial Services Markets Authority. The Prospectus will contain detailed information about the Company and its business, management, risks associated with investing in the Company, as well as financial statements and other financial data. This announcement cannot be used as basis for any investment agreement or decision.

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This announcement is only addressed to and directed at persons in member states of the European Economic Area ("EEA") other than Belgium who are "qualified investors" within the meaning of Article 2(1)(e) of the Prospectus Directive (Directive 2003/71/EC and amendments thereto, including Directive 2010/73/EU, to the extent implemented in the relevant Member State of the EEA, and together with any implementing measure in each relevant Member State of the EEA, the "Prospectus

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This announcement and the information contained herein does not constitute an offer to sell nor a solicitation to buy securities of the Company and it does not constitute a prospectus or a similar communication within the meaning of article 752, 652a and/or 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of the listing rules of the SIX Swiss Exchange.

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expectations concerning, among other things, its results of operations, prospects, growth, strategies and dividend policy and the industry in which the Company operates. By their nature, forward-looking statements involve known and unknown risks and uncertainties. New risks can emerge from time to time, and it is not possible for the Company to predict all such risks, nor can the Company assess the impact of all such risks on its business or the extent to which any risks, or combination of risks and other factors, may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements are not guarantees of future performance. Given these risks and uncertainties, the reader should not rely on forward-looking statements as a prediction of actual results. Without prejudice to the Company's obligations under applicable law in relation to disclosure and ongoing information, the Company does not intend, and does not assume any obligation, to update forward-looking statements.

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