

**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.**



## Press Release

### **UK NICE recommends use of the alfapump® for the treatment of refractory ascites caused by cirrhosis under special arrangements**

**Ghent, BELGIUM – November 15, 2018 – 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 UK National Institute for Health and Care Excellence (“NICE”) has published updated Interventional Procedures Guidance (“IPG”) supporting the use of the **alfapump®** for the treatment of refractory ascites caused by cirrhosis. The updated IPG recommends use of the **alfapump®** under “special arrangements for clinical governance, consent, and audit or research” and replaces the previous guidance of February 2014 recommending the **alfapump®** for “research use only”. The updated guidance is a result of the additional safety, efficacy and quality of life data published for the **alfapump®**.

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 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 for refractory ascites carry the risk of significant or life-threatening side effects, provide only short-term symptomatic relief or have very limited availability.

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. Clinical studies have demonstrated 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.

The new IPG recommends patient selection for the **alfapump®** to be done in specialist centers, by clinicians experienced in managing liver disease and in the various options available for managing ascites.

“Refractory ascites has a huge effect on a patient’s quality of life” **commented Judi Rhys, Chief Executive of the British Liver Trust.** “Those affected report feelings of isolation and depression as they cannot do their daily activities. The updated NICE guidance for the use of the **alfapump®** in patients suffering from this debilitating

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complication of liver disease is an important step forward for the patient community and their caregivers. We are enthused by the possible reduced hospital admissions and improved quality of life this new treatment option may offer.”

“The NICE guidance reinforces our strong conviction that the **alfapump**<sup>®</sup> has the potential to dramatically improve the lives of patients suffering from refractory ascites” **said Ian Crosbie, Chief Executive Officer at Sequana Medical.** “We are strongly committed to making the **alfapump**<sup>®</sup> available to those patients in need of a better alternative treatment that gives them and their family the chance of living a normal life again. The forecast growth in cirrhosis and refractory ascites as a result of NASH makes the need for a modern and convenient treatment option all the more important.”

#### **The offering**

KBC Securities and Kempen & Co are acting as Joint Global Coordinators and Joint Bookrunners. Mirabaud has been appointed as Lead Manager.

Subject to the approval of the prospectus by the Belgian Financial Services and Markets Authority ("FSMA") and market conditions, it is expected that the price range, as well as other details of the Offering will be published when the Offering period is expected to commence. After its approval, the prospectus is expected to be made available at the Company's registered office and on the websites of Sequana Medical ([www.sequanamedical.com](http://www.sequanamedical.com)) and KBC Securities NV/SA ([www.kbc.be/sequana](http://www.kbc.be/sequana), [www.bolero.be/nl/sequana](http://www.bolero.be/nl/sequana) and [www.kbcsecurities.com](http://www.kbcsecurities.com).)

The Offering is expected to consist of (i) a public offering in Belgium and (ii) private placements to institutional and other qualified investors in Belgium and elsewhere outside the United States. In the United States, only qualified institutional buyers are expected to be eligible, in accordance with an exemption from the registration requirements of the United States Securities Act of 1933, as amended.

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**ENDS**

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## Note to Editors

### About the NICE guidance for the alfapump®

The publication of the interventional procedures guidance has recommended use of the **alfapump**® for the treatment of refractory ascites caused by cirrhosis, with special arrangements for clinical governance, consent, and audit or research.

More information can be found on the NICE website at [www.nice.org.uk/guidance/ipg631](http://www.nice.org.uk/guidance/ipg631).

### About British Liver Trust

The British Liver Trust is the leading UK patient organisation supporting adults with liver disease and their families across the UK. They offer information and support, including a telephone Helpline, a range of publications and an online community with over 13,000 members. This is a nurse moderated forum where patients can access peer to peer support and discuss a range of topics including refractory ascites. For further information, please visit [www.britishlivertrust.org.uk](http://www.britishlivertrust.org.uk).

### 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 initial results were presented at the AASLD (American Association for the Study of Liver Diseases) in October 2017. 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 therapy ("DSR"), 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. Treatment of volume overload in diuretic-resistant 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.

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](http://www.sequanamedical.com).

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### **Important Regulatory Disclaimer**

Any statement in this press release about safety and efficacy of the **alfapump**<sup>®</sup> 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 that was announced by the Company on 8 November 2018 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").

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.

This announcement is not for distribution, directly or indirectly, in or into the United States or to any U.S. person within the meaning of the United States Securities Act of 1933, as amended (the "U.S. Securities Act"). It does not constitute or form a part of any offer or solicitation to purchase or subscribe for securities in the United States. The securities mentioned herein have not been, and will not be, registered under the U.S. Securities Act and may not be offered or sold in the United States, except pursuant to an exemption from, or in a transactions not subject to, the registration requirements of the U.S. Securities Act. The Company has not registered, and does not intend to register, any portion of the intended offering of the offered shares in the United States, and does not intend to conduct a public offering of securities in the United States.

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 Directive"). In addition, in the United Kingdom, this announcement is only addressed to and directed at (i) persons having professional experience in matters relating to investments falling within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order"), (ii) high net worth entities, etc. falling within Article 49(2)(a) to (d) of the Order, and (iii) any other person to whom it may otherwise lawfully be communicated (all such persons together being referred to as "relevant persons"). The intended offering, as the case may be, will only be available to, and any invitation, offer or agreement to subscribe for, purchase, or otherwise acquire securities will be engaged in only with relevant persons. Any person who is not a relevant person should not act or rely on this announcement or any of its contents.

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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The date of completion of listing on the regulated market of Euronext Brussels may be influenced by things such as market conditions. There is no guarantee that such listing will occur and investors should not base their financial decisions on the Company's intentions in relation to such listing at this stage.

Acquiring investments to which this announcement relates may expose an investor to a significant risk of losing the entire amount invested. Persons considering such investments should consult an authorised person specialising in advising on such investments. This announcement does not constitute a recommendation concerning the intended offering. The value of the shares can decrease as well as increase. Potential investors should consult a professional advisor as to the suitability of the intended offering for the person concerned.

No action has been taken by the Company that would permit an offer of Company's shares or the possession or distribution of these materials or any other offering or publicity material relating to such shares in any jurisdiction outside of Belgium where action for that purpose is required. The release, publication or distribution of these materials in certain jurisdictions may be restricted by law and therefore persons in such jurisdictions into which they are released, published or distributed, should inform themselves about, and observe, such restrictions. The issue, the subscription for or purchase of shares of the Company can be subject to special legal or statutory restrictions in certain jurisdictions. The Company is not liable if the aforementioned restrictions are not complied with by any person.

The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements". In some cases, forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should" or, in each case, their negative or other variations or comparable terminology or by discussions of strategies, plans, objectives, targets, goals, future events or intentions. Forward-looking statements include statements regarding the Company's intentions, beliefs or current 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.

KBC Securities NV/SA, Kempen & Co N.V. and Mirabaud Securities Limited (the "Underwriters") are acting for the Company and no one else in relation to the intended offering, and will not be responsible to anyone other than the Company for providing the protections offered to their respective clients nor for providing advice in relation to the intended offering.

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