Sequana Medical announces results of Annual General Meeting of Shareholders

Experienced MedTech Executive Jason Hannon appointed as Non-Executive Director

Ghent, BELGIUM – 23 May 2019 (18:00 CEST) – 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, announces today that the proposed resolutions presented at its Annual General Meeting of Shareholders (AGM) were duly passed at the meeting, which was held today at 9:00 CEST.

Resolutions approved at today's AGM included the appointment of Mr. Jason Hannon as independent nonexecutive director of the Company. Shareholders also approved resolutions relating to the financial year, which ended 31 December 2018. All documents can be accessed on the <u>Company's website</u>.

Mr. Hannon has extensive experience in the medical device industry and is currently Chief Executive Officer at Mainstay Medical International, a global medical device company focused on the development and commercialisation of an innovative implantable neurostimulation system designed to treat chronic lower back pain. Prior to joining Mainstay, Mr. Hannon served as President and Chief Operating Officer of NuVasive (NASDAQ:NUVA), a leading medical device company focused on transforming spine surgery with minimally disruptive, procedurally-integrated solutions. He helped grow NuVasive from a small U.S.-centric business with a handful of products into the third largest spine company in the world.

Pierre Chauvineau, Chairman of Sequana Medical, commented: "We are delighted to welcome Jason Hannon to Sequana Medical. His significant knowledge of the medical device industry and his experience in leading international businesses will greatly benefit the Company and we look forward to working with him."

Commenting on his appointment, Jason Hannon added: "I am excited to be joining Sequana Medical during this important time of growth for the Company, as it prepares to expand its **alfa**pump business in North America and in the field of heart failure with its innovative DSR (Direct Sodium Removal) therapy. I look forward to working with the team and contributing to this exciting journey."

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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 due to cancer. 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. The **alfa**pump has been endorsed by key independent third parties in Europe and has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for decompensated cirrhosis, the German treatment guidelines (DGVS) for complications of liver cirrhosis and the U.K. NICE interventional procedure guidance for treatment of refractory ascites caused by cirrhosis. In January 2019, the U.S. FDA granted Breakthrough Device designation for the **alfa**pump for the treatment of recurrent or refractory liver ascites. The Company expects to start POSEIDON, the North American pivotal study in the second half of 2019 to support approval of the **alfa**pump in recurrent or refractory liver ascites.

Sequana Medical has leveraged its **alfa**pump experience and is developing **alfa**pump DSR (Direct Sodium Removal) to deliver a convenient and fully implanted system for DSR therapy, its novel and proprietary approach for the management of volume overload in patients suffering from heart failure. DSR therapy involves the removal of sodium via diffusion from the body into the peritoneal cavity by administering a sodium-free solution ("the DSR infusate") into the abdomen. The DSR infusate and the extracted sodium are then removed using the **alfa**pump and the body responds by eliminating the excess fluid via osmotic ultrafiltration (the movement of water, together with sodium, from the bloodstream to the peritoneal cavity) and/or urination. Volume overload in the body is a major clinical problem in heart failure, a condition that results in \$13 billion of U.S. hospital admission costs annually.

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 as a late-breaking oral presentation at Heart Failure 2019 on 27 May 2019. The repeated dose **alfa**pump DSR heart failure study is expected to start in the second half of 2019.

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

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 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 forwardlooking 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.