PRESS RELEASE

REGULATED INFORMATION – INSIDE INFORMATION

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Sequana Medical announces €7.3 million debt financing and provides clinical update

- **Cash runway extended into H2 2021 enabling Sequana Medical to reach key near term value inflection points**
- **POSEIDON – implants resumed and interim results expected in Q1 2021 (North American pivotal study of the** alfa**pump® in patients with recurrent or refractory ascites due to liver cirrhosis)**
- **RED DESERT – implants resumed and interim results anticipated in Q4 2020 and top-line results in Q1 2021 (repeated dose study of the** alfa**pump DSR in diuretic-resistant heart failure patients)**

Ghent, BELGIUM – 28 July 2020 – Sequana Medical NV (Euronext Brussels: SEQUA) (the "**Company**" or "**Sequana Medical**"), an innovator in the management of fluid overload in liver disease, malignant ascites and heart failure, today announces it has secured a €7.3 million debt financing through subordinated loan agreements, of which €1.4 million will be convertible for new shares of the Company.

The funding extends the cash runway into H2 2021 and enables the Company to reach key clinical milestones in its North American liver and global heart failure programmes. A detailed financial update will be provided in the half year results which will be announced on 3 September 2020.

"We are pleased to have successfully secured this additional funding at attractive terms, especially given the current volatile financial markets", **said Kirsten Van Bockstaele, Chief Financial Officer at Sequana Medical. "**With this financing in place, we are well-placed to continue to execute on our strategy and to reach our next value inflection points, expected in the coming months."

The Company also announces an update on timings of its clinical development programmes, following the impact of the ongoing COVID-19 global health crisis.

The **POSEIDON North American pivotal study** of the **alfa**pump in recurrent and refractory ascites due to liver cirrhosis has resumed its recruitment activities in Canada. In the U.S., while travel restrictions and restrictions on non-essential hospital visits and procedures are still in place, patients continue to be screened for recruitment into the study. Subject to further developments related to the COVID-19 pandemic, patient recruitment in the U.S. is expected to resume early in Q4 2020 with interim results expected in Q1 2021. The Company anticipates to complete enrolment by the end of 2020 with a primary endpoint read-out by the end of 2021. The POSEIDON study aims to support the approval of the **alfa**pump in the U.S. and Canada, with an FDA submission expected in H1 2022.

Enrolment of the **RED DESERT repeated dose proof-of-concept study** of the **alfa**pump DSR (Direct Sodium Removal) for the treatment of diuretic-resistant heart failure patients has also resumed and the Company now expects to report interim results in Q4 2020 and top-line results in Q1 2021. The RED DESERT interim results in Q4 2020 are intended to support the discussions with the U.S. FDA to reach agreement on the plans for a U.S. feasibility study of the **alfa**pump DSR in patients with volume overload due to heart failure, which is expected to be initiated in H2 2021.

Ian Crosbie, Chief Executive Officer at Sequana Medical, said: "As Sequana Medical swiftly resumes its operations following the clinical trial enrolment delays related to COVID-19, we are pleased to report that the interest from patients and the medical community in our innovative treatment approaches remains extremely

high. The quality of our team and of our products, combined with this new financing, will enable us to continue the strong momentum in our development programs. We are excited at the prospect of bringing these breakthrough devices to patients as soon as possible and to continue to deliver strong value to all our stakeholders."

Details of the €7.3 million debt financing

The Company entered into subordinated loan agreements with several shareholders, including PMV/z-Leningen, for an aggregate principal amount of €7.3 million, of which €1.4 million can be converted by the lenders into new shares of the Company in the event of a future equity financing or sale of the Company.

The loans have a term of 36 months and are repayable in full upon expiry of the term. The loans bear an interest of 6% per annum, except that the convertible portion of the loans bear an interest of 5% per annum. The interest is payable only upon expiry of the term of the loans. The price per share at which the convertible portion of the loans can be converted in the event of an equity financing or sale of the Company will be equal to 75% of the price of the Company's shares as will be reflected in the equity financing or sale.

The loan by PMV/z-Leningen is part of the action plan of the Flemish Region to support businesses as a result of the COVID-19 crisis.

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About the POSEIDON study

POSEIDON is a prospective, single-arm, open-label study and is expected to include up to 50 patients to be implanted with the **alfa**pump in approximately 20 centres across the U.S. and Canada for primary endpoint analysis. The primary effectiveness outcome of the study will include the proportion of patients with a 50% reduction in overall average frequency of paracentesis per month post-implantation versus pre-implantation. This endpoint will be evaluated at nine months after enrolment. Patients will be followed for up to two years after implantation for analysis of secondary outcome measurements. First patients were enrolled in the study in H2 2019. For more information about the study, please visit clinicaltrials.gov (NCT03973866).

About the RED DESERT study

RED DESERT is a prospective, single-arm, repeated dose study and is expected to include up to 10 heart failure patients, who are on high dose diuretics, to be implanted with the **alfa**pump DSR across two centres in Belgium and Georgia. The primary safety endpoints include the rate of device, procedure and/or therapy-related serious

adverse events after two and six weeks. The secondary endpoints include the feasibility of **alfa**pump DSR to remove excess sodium and fluid from the body, thereby eliminating the need for daily high dose diuretics during the six-week treatment period. Additional exploratory endpoints to measure the potential impact of DSR therapy to restore response to diuretics will be evaluated through week six. First patients were enrolled in the study at the end of 2019. For more information about the study, please visit clinicaltrials.gov (NCT04116034).

About Sequana Medical

Sequana Medical is a commercial stage medical device company developing the **alfa**pump platform for the management 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. 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 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. The North American pivotal study (POSEIDON) in recurrent and refractory ascites due to liver cirrhosis is currently underway, and is intended to support a commercial 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 a repeated dose **alfa**pump DSR study (RED DESERT) in heart failure patients is currently underway.

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

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 and the **alfa**pump DSR are 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, **alfa**pump DSR 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.