

## Sequana Medical appoints two additional experts as Heart Failure Scientific Advisors

Dr. Felker and Dr. Udelson join current advisors to support the development of **alfa**pump® DSR for the management of fluid overload in patients with heart failure

**Ghent, BELGIUM – 15 October 2020 – Sequana Medical NV (Euronext Brussels: SEQUA)**, an innovator in the management of fluid overload in liver disease, malignant ascites and heart failure, today announces the appointments of Dr. Michael Felker and Dr. James Udelson as new Heart Failure Scientific Advisors.

They join current advisors Dr. Javed Butler, Dr. Maria Rosa Costanzo, Dr. Wilson Tang and Dr. Jeffrey Testani as <u>Heart Failure Scientific Advisors to Sequana Medical</u>. The Sequana Medical management team is working closely with its advisors on the development of **alfa**pump DSR (Direct Sodium Removal).

Built on its proven **alfa**pump platform, **alfa**pump DSR is Sequana Medical's breakthrough approach for the management of fluid overload in patients suffering from heart failure. Pre-clinical and clinical proof-of-concept data from a first-in-human single dose DSR study demonstrated that single dose DSR therapy was safe and well-tolerated and the positive results were published in the high impact peer-reviewed cardiovascular journal, *Circulation*. Sequana Medical is currently conducting RED DESERT, a repeated dose **alfa**pump DSR study in diuretic-resistant heart failure patients and expects to report interim results in Q4 2020 and top-line results in H1 2021.

"There is an urgent medical need for new treatment options for diuretic-resistant heart failure patients and I look forward to working with the Sequana Medical team and advisors to support the ongoing development of alfapump DSR to address this need," said Dr. Felker. "The alfapump DSR has the potential to offer a much-needed alternative treatment option for this underserved patient population, who are so challenging to treat with current therapies. Sequana Medical has made good progress with the alfapump DSR with impressive preclinical and early clinical data, and I look forward to playing a part in the ongoing development of this exciting product," added Dr. Udelson.

"I am delighted that Dr. Felker and Dr. Udelson have agreed to join our group of Heart Failure Scientific Advisors – they are renowned experts in the field and their knowledge and experience, alongside that of our existing advisors, will be invaluable as we work to bring alfapump DSR to this large patient group that has limited current options", said Ian Crosbie, Chief Executive Officer of Sequana Medical. "The global heart failure market represents a tremendous opportunity for Sequana Medical and we look forward to providing an update on the interim results from our RED DESERT study later this year."

#### **About Dr. Felker**

G. Michael Felker, MD, MHS, FACC, FAHA, FHFSA is Professor of Medicine with tenure in the Division of Cardiology at Duke University School of Medicine. He is Director of Cardiovascular Research at the Duke Clinical Research Institute and Vice-Chief for Clinical Research in the Division of Cardiology. Dr. Felker's research focus is on clinical trials in acute and chronic heart failure and the use of biomarkers as diagnostics, prognostic, and therapeutic tools in heart failure. He has published over 320 peer reviewed articles and book chapters in the field of heart failure and has served on the executive and steering committees for multiple national and international clinical trials in heart failure. Previously, he was Chief of the Heart Failure Section at Duke University School of Medicine from 2013 to 2020.

#### **About Dr. Udelson**

James E. Udelson, MD is Chief of the Division of Cardiology at Tufts Medical Center and Professor of Medicine and Radiology at Tufts University School of Medicine. Dr. Udelson's research interests involve studying the effects of new therapeutic modalities in the setting of heart failure as well as acute and chronic coronary artery

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disease, and the development of imaging modalities to assess those effects. Dr. Udelson has directed and/or participated in numerous clinical trials on heart failure and cardiac imaging, focusing on the role of new therapies and how they affect remodeling, physiology, function, and outcomes. Dr Udelson has served as a member of the FDA Medical Imaging Drugs Advisory Panel and has been invited as an ad hoc member of the FDA's Cardiovascular and Renal Drugs Advisory Panel and the Peripheral and Central Nervous System Advisory Panel.

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#### **About Sequana Medical**

Sequana Medical is a commercial stage medical device company developing the alfapump 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 alfapump resulting from NASH-related cirrhosis is forecast to exceed €3 billion annually within the next 10-20 years. The heart failure market for the alfapump 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 alfapump, 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® 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

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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.

#### 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.