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Sequana Medical receives CE Mark Approval for the ALFApump System and adds Key Executive to Team

Switzerland (ots) -

New technology expands treatment options for patient with refractory ascites due to liver cirrhosis. Dr. Farzana Malik joins as Vice President of Market Access and Reimbursement.

Sequana Medical announced today that it has received CE Mark approval for the commercial sale of its ALFApump System. Over the coming months, the company will launch the product in selected hepatology and liver transplant hospitals across Europe. The ALFApump System is indicated for the management of refractory and recurrent ascites due to liver cirrhosis, a condition where massive and uncontrolled fluid accumulation occurs in the abdominal cavity.

"This is a major milestone both for our company and for patients with refractory ascites," stated Dr. Noel L. Johnson, CEO of Sequana Medical. "For patients, the treatment options for refractory ascites have been very limited and carried significant risks and side effects. The ALFApump System offers a new treatment tool which can improve patient quality of life while also reducing hospitalizations. It is a cost-effective solution and we believe over time it will become the preferred option for patients, physicians and payers. We are eager to begin our commercial launch in Europe."

Sequana Medical's ALFApump System is a proprietary implantable pump system designed to remove excess abdominal fluid, known as ascites, in patients suffering from liver cirrhosis. The ALFApump System consists of a subcutaneously implanted battery-powered pump with a catheter placed in the abdominal cavity and another catheter connected to the bladder. The ALFApump System automatically and continually collects fluid as it forms in the abdominal cavity and moves it to the bladder, where it is eliminated through normal urination. The ALFApump is recharged wirelessly and can be programmed to meet the unique needs of each patient.

Refractory ascites occurs when patients with ascites no longer respond to medical therapy. This condition affects over 100,000 patients in Europe and the US every year. The number of patients suffering from ascites is growing at approximately 10% a year due to the accelerating incidence of hepatitis- and obesity-related liver disease. The primary treatment for ascites is paracentesis, a procedure in which a large bore needle is inserted into the patient's abdomen to remove between 5-10 liters of ascites that has accumulated over a period of a week or two. The cumulative cost of ascites-related care for these patients often exceeds \$50,000 each year.

"The benefits of the ALFApump System are entirely aligned with the goals of patients, physicians and payers," commented Dan Rose, VP of Commercial Operations. "The system is designed to offer patients better clinical outcomes and quality of life while eliminating the requirement for repeated expensive and burdensome invasive procedures. The performance of the ALFApump System in the PIONEER Clinical Study has surpassed our expectations and indicates a bright future for our technology as a new treatment option. We look forward to partnering with leading hepatology centers as we launch the ALFApump System in Europe."

In May, Sequana Medical completed full enrollment of its 40-patient PIONEER Study, a prospective, multi-center, open label study of patients with refractory ascites due to liver cirrhosis. The PIONEER Study was designed to evaluate the safety and performance of the ALFApump System in obviating the need for paracentesis, the standard therapy for patients with refractory ascites. The Study was completed in 9 centers across 4 European countries. Dr. Jose Such, the principle investigator of the Pioneer Study, stated that, "The ALFApump System CE Marking is great news for both Sequana Medical and for my patients with refractory ascites."

Additionally, Sequana Medical is pleased to announce the appointment of Dr. Farzana Malik as Vice President of Market Access and Reimbursement. "Dr. Malik is a Health Economist and brings over 15 years expertise in developing and executing health economics, pricing and reimbursement strategies in the biotechnology, pharmaceutical and medical device industries," said Dr. Johnson. She comes to Sequana Medical from Alexion Pharmaceuticals, where she was Head of Pricing and Market Access. Previously, she held positions at Merck Serono, Medtronic and Pfizer.

About Sequana Medical:

Sequana Medical is a Swiss medical device company dedicated to improving patient lives through innovative technologies to manage fluid within the body.

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