

## Press Release

### **Sequana Medical receives CE-mark approval for the use of its **alfapump**<sup>®</sup> system in cancer patients with malignant ascites**

Zürich, SWITZERLAND – 30. Oct, 2012

Sequana Medical is pleased to announce that it has received CE mark approval for use of its **alfapump**<sup>®</sup> system in patients with ascites caused by cancer (malignant ascites). The **alfapump**<sup>®</sup> system was first introduced to the European market last year for patients with refractory ascites caused by advanced liver disease. The system is fully implantable, and automatically and continually collects ascites from the abdominal cavity and moves it to the bladder, where it is excreted naturally from the body.

Malignant ascites is an excess build-up of fluid in the abdominal cavity and is a common complication among patients with ovarian, pancreatic and gastric cancer. It is usually managed with large-volume paracentesis, an invasive hospital-based procedure in which the ascites is drained over a number of hours through a large-bore needle inserted in the abdomen.

“CE mark approval of the **alfapump**<sup>®</sup> system for patients with malignant ascites is a major milestone for Sequana Medical”, stated Noel L. Johnson, President and CEO of Sequana Medical. “Malignant ascites affects more than 20,000 people per year in the EU. Our system was designed to improve quality of life, so we are very pleased indeed that cancer patients with ascites will now also be able to benefit from our technology.”

Patients no longer experience the discomfort of chronic ascites accumulation and they no longer have to make regular trips to the hospital for paracentesis. By decreasing hospitalization time, the **alfapump**<sup>®</sup> system reduces the burden of ascites for patients, physicians and the healthcare system.

“This is an exciting development. The **alfapump**<sup>®</sup> system hopes to provide malignant ascites patients with a much-needed new treatment option,” commented Professor Hani Gabra, Professor of Medical Oncology at Imperial College London. “Furthermore, there is enormous potential for this technology in the field of personalized medicine. Ascites can be easily collected via urine sample and then analyzed

to determine the presence of certain biomarkers. We are evaluating such urine derived tumour cells and this will allow the physician to quickly identify changes in the disease state and tailor patient treatment accordingly, with a view to improving outcomes”.

Sequana Medical’s PIONEER study, a 40-patient non-randomized trial which concluded in 2011, clearly demonstrated the safety and performance of the **alfapump**<sup>®</sup> system and demonstrated a significant reduction in the requirement for paracentesis. Several follow-up studies are currently in the pipeline, including AMAZE, a 50-patient randomized controlled trial in ovarian cancer patients suffering from ascites. This trial will be led by Professor Gabra of Imperial College London.

**About Sequana Medical:**

Founded in 2006, Sequana Medical AG is a Swiss medical device company backed by NeoMed Management, VI Partners, Biomed Invest, Capricorn Health Tech and Entrepreneur’s Fund, dedicated to improving patient lives through innovative technologies to manage fluid overload in patients suffering from liver disease, cancer and congestive heart failure.

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