

First US FDA Submission of Wearable Drug-Device Combination Product Based on Sensile Medical's SensePatch Drug Delivery Technology

Olten, Switzerland, November 6th, 2017

Sensile Medical, a global leader in Large Volume Injector devices based on the cost-efficient and highly accurate SenseCore micro pump technology platform, today announced that scPharmaceuticals has submitted Furosemide for s.c. administration together with Sensile's patch pump delivery system for approval with the U.S. Food and Drug Administration (FDA). This represents the first regulatory submission in the United States for Sensile Medical's SensePatch technology as a combination product with scPharmaceuticals' Furosemide for use in the United States.

The NDA for the combination product of a novel furosemide formulation and sc2Wear Infusor™ based on the SenseCore micro pump technology was submitted in August and has been accepted for filing by the U.S. Food and Drug Administration (FDA). Under the Prescription Drug User Fee Act (PDUFA), the FDA has set an action date of June 23, 2018.

"The NDA submission and FDA acceptance of the filing of this large-volume innovative drug-device product represents an important milestone for Sensile Medical and for the emerging market of wearable drug delivery devices," said Derek Brandt, CEO of Sensile Medical. "The lessons learned during the design and development process position us well to pursue this platform across a broad range of therapeutic segments and uses."

Advantages of Subcutaneous Drug Delivery Using Sense Core Technology

Slow and controlled subcutaneous drug delivery is often therapeutically equivalent to intravenous (IV) or intramuscular (IM) drug administration. Contrary to IV or IM drug administration, subcutaneous delivery is something patients or lay caregivers can usually do in the comfort of their home. This enables novel, hospital-strength treatment options for home use.

Sensile's unique SenseCore micro-pump technology powers a new generation of large volume devices as well as pumps for very exact small volume delivery. The SenseCore allows for a first of its kind device design that uses a reusable motorized component and disposable cartridges. This design minimizes waste and creates cost-effective treatment options unattainable by other device technologies.

For more information about the SensePatch platform and the SenseCore technology, visit www.sensile-medical.com

About Sensile Medical

Sensile Medical AG is a leading company in the area of advanced micro pump technology developing a broad range of customer-specific delivery and dosing solutions. These pumps are ideally suited for Large-Volume subcutaneous delivery of modern pharmaceutical and biotech products for self-administration by patients. Due to Sensile Medical's unique SenseCore technology the products are highly cost-efficient, accurate, and safe. They are increasingly used in drug delivery, medical and consumer applications. Founded in 2004, Sensile Medical is located in Olten, Switzerland.

Media Contact



Sensile Medical AG

Monika Kammermann
Solothurnerstr. 235
CH-4600 Olten
Switzerland
monika.kammermann@sensile-medical.com
Phone: +41 (0) 62 209 71 00