

Patient recruitment completed for the first clinical study investigating Sensimed Triggerfish® in the USA



Lausanne, November 2nd, 2011. Swiss-based company Sensimed has developed the SENSIMED Triggerfish®, a revolutionary contact lens for the continuous monitoring of fluctuations in intraocular pressure to facilitate the management of glaucoma. Sensimed announced today the completion of the first clinical study investigation in the USA.

SENSIMED Triggerfish® is considered to be a non-significant risk (NSR) device for the conduct of clinical investigation in the USA following recent consultation with FDA. As such, the medical device may be investigated in clinical studies upon the investigational sites Institutional Review Board (IRB). Two studies are underway in the USA.

A prospective, open label clinical study has been designed to investigate the safety and tolerability of using SENSIMED Triggerfish® in 40 glaucoma suspects or patients with primary open angle glaucoma (POAG). The study has recently completed subject accrual, and ambulatory subjects were exposed to two consecutive 24-hour SENSIMED Triggerfish® sessions 7 days apart (Clinicaltrials.gov identifier: NCT01319617).

A forthcoming open label study to assess the efficacy of the 24-hour IOP SENSIMED Triggerfish® recording during wake and sleep as compared to tonometry in patients with POAG is actively recruiting patients at the sleep-lab in the same center. The study aims to recruit 30 eligible patients. In addition to safety, further assessments include the correlation between the ocular pulsation frequency and heart rate. Patient acceptance of SENSIMED Triggerfish® wear will be measured by means of a Visual Analog Scale. Furthermore there will be categorization of subject diurnal rhythm of IOP as measured by SENSIMED Triggerfish® and assignment to pre-specified diurnal rhythms identified from the literature (Clinicaltrials.gov identifier: NCT01390779).

Sensimed has also initiated several clinical studies to assess the efficacy and safety of SENSIMED Triggerfish® both in healthy subjects and patients with glaucoma at investigational sites in a number of European member states and South-East Asia.

About SENSIMED:

Established in 2003, Sensimed AG is a Swiss company with its principal focus on design, development and commercialization of integrated micro-systems for medical devices. Sensimed was spun off from the well renowned Swiss Federal Institute of Technology (EPFL) and grows within a world-leading cluster for medical devices in the lake of Geneva area. Sensimed has developed a new, patented, non-invasive product that will significantly improve identification and treatment of glaucoma disease by monitoring intraocular pressure around the clock.

www.sensimed.ch