Sensimed announces first-of-a-kind product approval for its Contact Lens based sensing device by U.S. FDA

Lausanne, Switzerland, March 15th 2016, Sensimed AG is pleased to announce the marketing clearance of its first-of-kind product, the SENSIMED Triggerfish®, by the U.S. Food and Drug Administration (FDA).

The SENSIMED Triggerfish® is a unique sensor-embedded contact lens based system that Sensimed developed with the aim to improve the management of glaucoma. Combining a fully integrated sensor and telemetry, it provides a wireless automated recording of continuous ocular dimensional changes over the course of 24 hours. This first-of-a-kind measurement parameter whilst, closely correlated with intra-ocular pressure (IOP) is a unique measure in itself. A recent study[1] published in *Ophthalmology* linked this unique continuous volumetric eye measurement to glaucoma disease progression and concluded that the SENSIMED Triggerfish® "may be useful in detecting eyes at higher risk of glaucoma progression while receiving treatment".

The FDA reviewed the SENSIMED Triggerfish® application through the De Novo Process used for first-of-a-kind technologies that are not substantially equivalent to an already marketed device. The SENSIMED Triggerfish® was classified in the newly created category entitled Diurnal Pattern Recorder System, defined as:

A diurnal pattern recorder system is a non-implantable, prescription device incorporating a telemetric sensor to detect changes in ocular dimension for monitoring diurnal patterns of intraocular pressure (IOP) fluctuations.

The device has been approved with the following indication:

The SENSIMED Triggerfish® is a prescription device indicated to detect the peak patterns of variation in intraocular pressure over a maximum period of 24 hours to identify the window of time to measure intraocular pressure by conventional clinical methods. The SENSIMED Triggerfish® is indicated for patients 22 years of age and older.

William Maisel, M.D., M.P.H., acting director of the Office of Device Evaluation in the FDA's Center for Devices and Radiological Health commented in their official release: "The Triggerfish gives the clinician 24-hour continuous monitoring of changes in IOP patterns that otherwise could not be obtained". He added: "This information can help determine the most critical time of day for the clinician to measure the patient's IOP."

"We are delighted to have worked closely with FDA on this De Novo application and to have gained approval for this first-of-a-kind contact lens-based sensing device in the USA", said David Bailey, the CEO of Sensimed. "There is a very strong interest within the ophthalmic community for the whole concept of contact-lens based sensing and we are extremely proud to have created and developed the first ever product approved in this category."

[1] *Visual Field Change and 24-Hour IOP-Related Profile with a Contact Lens Sensor in Treated Glaucoma Patients, De Moraes C. G. et al. – Ophthalmology, in Press*

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innovation in medical micro-technology

"Thanks to the remarkable work of our in-house Team in cooperation with our clinical collaborators and advisors, we overcame many technical hurdles to make contact lens sensing a reality and become the very first company to gain FDA endorsement for such a device. We view this as a pivotal platform approval that will allow us to both expand indications for the current product and to explore other potential applications for this first-of a kind on eye sensing technology."

"Although with this approval we have obtained US marketing clearance, our goal for the upcoming months is not to immediately launch the product but rather to work closely with the Glaucoma community to design and execute a major post-approval study to confirm the use of the SENSIMED Triggerfish® signal to predict the course of progression of the disease. The overall aim is to build additional clinical utility for the device and establish ocular volume change patterns as a significant stand-alone reference biomarker for use in the management and treatment of Glaucoma", he added.

About Sensimed:

FROM DEVICE TO KNOWLEDGE -- Sensimed AG, a Swiss company, has developed a unique non-invasive soft contact lens-based solution, the SENSIMED Triggerfish®, with the aim of revolutionizing glaucoma management by providing an automated recording of continuous ocular dimensional change over 24 hours. The Company is currently expanding the knowledge of how this individual data can best be used in the clinical setting to deliver customized treatment. The 24 hour profiles are being centralized on a registry together with patient and treatment information. The data are analyzed and modeled on an ongoing basis in an attempt to identifying pathological patterns that can be used to differentiate between indications, personalize treatment and assess efficacy following treatment. The Company is directly positioned at the convergence between devices, treatment and information. Sensimed believes that with this global knowledge based approach we will be able to provide valuable insights that will allow ophthalmologists to better understand and treat glaucoma.

For further information about Sensimed see: www.sensimed.ch

About glaucoma:

Glaucoma is an asymptomatic, progressive and irreversible disease that leads to blindness unless adequate treatment is provided. Glaucoma is the second most common cause of blindness worldwide and affects about 70 million people. Abnormal intraocular pressure is a known cause of glaucoma. This behavior is individual, has transient peaks and varies significantly over a 24 hour period. By providing ophthalmologists with the 24 hour profile of ocular dimensional changes related to intraocular pressure, the SENSIMED Triggerfish® helps the doctor to better understand the condition of the patient and to provide personalized treatment.

About FDA:

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

For further information about FDA see: www.fda.gov

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