

## Sensimed announces PMDA approval of the SENSIMED Triggerfish® in Japan



Lausanne, Switzerland, October 3<sup>rd</sup> 2018, Sensimed is pleased to announce the registration of the SENSIMED Triggerfish® sensor and monitoring system as a medical device in Japan.

The Japanese partner and distributor of Sensimed, SEED Co., Ltd., has obtained the approval from the Ministry of Health, Labour and Welfare. The device will be available for sale towards the end of 2018.

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 product received the CE mark in 2010 and was approved by the U.S. Food and Drug Administration (FDA) in 2016.

The contact lens sensor itself is very well tolerated over the measurement period and uses telemetry in combination with a fully integrated sensor to measure volumetric change of the eye. To date, Sensimed has published over 40 peer review articles in respected ophthalmic journals to support these conclusions. This completely new measurement is highly correlated with intraocular pressure change and has been shown to be lined to previous rate of progression data.

Sensimed continues its close collaboration with SEED who have a very strong organization to support the launch of this first of a kind smart contact lens in the Japanese market. Besides preparing for the establishment of a sales structure for the Japanese market, the two companies intend to quickly accumulate clinical data from specialized medical centers focused on confirming medical utility of the SENSIMED Triggerfish® in the field of glaucoma. The focus in Japan will be on the significant pool of patients who have normal tension glaucoma (NTG) where standard IOP measurement tools are inadequate and where there is a large unmet need for an alternate diagnostic tool. The 24-hour profiles provided by the device, linked with the disease progression, will be analyzed and modeled in an attempt to confirm pathological patterns that can be used to categorize the disease state and aid personalized treatment.

“We believe that it can significantly reduce the burden of night time IOP measurements while at the same-time help with the categorization of NTG patients” – stated David Bailey CEO of Sensimed. In gaining this approval both companies have received significant support from key opinion leaders representing the Japanese glaucoma society in working with PMDA to create this new category of smart contact lens. Both SEED and Sensimed will continue to actively collaborate in other areas of the sensing contact lens business – Sensimed is currently using the same technology platform as the SENSIMED Triggerfish® to bring to market a pressure sensing contact lens measuring IOP in standard units over a 24-hour period. Initial clinical trials have been completed and the results clearly demonstrate success with this revolutionary noninvasive technology.

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 now focused on 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 identify 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](http://www.sensimed.ch)*

About SEED:

SEED has been supplying a wide range of contact lenses and other eye care products for more than sixty years with international presence in Asia and Europe. In 2017, SEED began exports to India, Indonesia, Portugal, Switzerland and the Netherlands. To date, SEED products are available in 24 countries. Last March, SEED's stocks were transferred to the 1<sup>st</sup> section of Tokyo Stock Exchange following its approval, with a market capitalization of JPY57.6Bn as of 26<sup>th</sup> September 2018. SEED recently acquired Contact Lens Precision laboratories Ltd, the holding company of UltraVision Ltd, in the UK.

*For further information about SEED see: [www.seed.co.jp/en/index.html](http://www.seed.co.jp/en/index.html)*

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.

**Contact Sensimed:**

Sensimed AG  
Eva Pataki  
[eva\\_pataki@sensimed.ch](mailto:eva_pataki@sensimed.ch)  
Tel: +41 21 621 9191

SENSIMED AG

Route de Chavannes 37 • 1007 Lausanne • Switzerland  
Tel. +41 21 621 9191 • Fax. +41 21 621 9193  
[www.sensimed.ch](http://www.sensimed.ch) • [info@sensimed.ch](mailto:info@sensimed.ch)