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Sensimed's Triggerfish glaucoma-monitoring device may get FDA 510k approval by year-end - CEO

Sensimed's Triggerfish for 24-hour monitoring of intraocular pressure (IOP) in glaucoma patients may get US Food and Drug Administration (FDA) 510k approval by the year-end , according to CEO Jean-Marc Wismer.

The Swiss ocular device company will close the first USD 10m tranche of its USD 20m Series C fundraising shortly. The first half has been successful, and the company will likely not work on the second tranche until early next year, said Wismer.

The single-use contact lens sensing device, which sends IOP data via a wireless signal to an antenna, has held a CE mark since 2009 and is sold in close to 30 countries, he said.

Additionally, the company has started registration in China where glaucoma is a significant problem, the CEO said. Wismer expects Triggerfish to be marketed in China late next year.

The device is also currently in approximately 20 trials at various centers around the world. The aim is to determine the safety of the device as well as various features of IOP such as fluctuation in and out of sleep and during physical activity. The trials are typically small and short, with 20-40 patients lasting three or four months, he added.

The device gives new information for glaucoma patients and physicians to use, said Kaweh Mansouri, consultant for Sensimed and senior fellow, department of ophthalmology, Hamilton Glaucoma Center, University of California, San Diego. Researchers can study IOP fluctuations during specific activities like jogging or yoga or the effect of different sleep positions, he explained.

It will help doctors better understand their glaucoma patients who seem to have well controlled IOP but still see disease progression, added Mansouri.

Tonometry, the gold standard for measuring IOP, is about 60 years old and gives the ophthalmologist a brief data point, once or twice a year, he said, adding that this is widely believed to be insufficient and probably explains why many patients who seem to have controlled IOP continue to get worse.

The current treatment strategy resembles a trial and error process in which the doctor sees the patient, measures, treats and might not see the patient again for a month or even a year, Mansouri said, noting that doing this, patients can lose years of precious time.

The device has clearly generated strong interest from large medical device companies as well as pharmaceutical companies, said Wismer. The device could have strong synergy for glaucoma-focused drug companies hoping to combine IOP data with treatments to help physicians individualize therapy, he noted.

Moving forward the challenge will be interpreting this new data as it opens glaucoma specialists up to an entirely new language, said Mansouri. Compared to previous measurements, there will be a wealth of data of relative nature. It will be a challenge to interpret this information and what it means for a patient's disease, progression and treatment outcomes, he said.

Sensimed receives financial consulting from Credit Suisse. The company uses two Swiss law firms and a US firm, but Wismer would not disclose their identities.

by Casey McDonald in New York

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