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SOLX receives CE approval for implantable gold micro-shunt

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Chicago—CE approval has been granted for SOLX's 24-karat DeepLight Gold Micro-Shunt (GMS), which is available for sale outside the United States for the first time. GMS results to date have shown remarkable IOP reduction without a bleb, according to the company. The announcement was made during a press briefing Friday at the American Academy of Ophthalmology.



Robert M. Kershner,
MD

GMS clinical results submitted to the European Agency for the Evaluation of Medicinal Products (EMA) included 70 eyes with primary open-angle glaucoma failed on maximum medical therapy as well as at least one surgical intervention. During a minimally invasive procedure, the ultra-thin GMS was inserted through a 4-mm wide incision connecting the anterior chamber and the suprachoroidal space. Eyes in the study were followed up for 2 years and have demonstrated more than 34% reduction compared with best medicated baseline. Complications and adverse events with the GMS were low and transient in almost all cases, especially as compared with the reported complications and adverse events associated with blebs.

"We consider CE approval of the gold micro-shunt to be a major milestone for SOLX," said Doug Adams, president and chief executive officer of SOLX. "Now that both components of the DeepLight Glaucoma Treatment System—the 790 Titanium Sapphire Laser and Gold Micro-Shunt—have been approved by the EMA, SOLX is one step closer to our goal of a future in which no glaucoma patient is required to take more than one medication."

The press event also included a presentation by Robert M. Kershner, MD, Eye Laser Consulting, Boston, on glaucoma therapy as well as some of the technical aspects of the system and an update on study data.

Plans call for clinical trials to begin soon both overseas and within the United States. The company has a goal of enrolling up to 500 eyes in its study.

More information is available at the SOLX Booth 227.

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