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Glaukos Submits PMA For iStent, Second-Generation MIGS Device For Treating Glaucoma

by Marion Webb

Glaukos Corp. announced on Dec. 27 it has submitted a pre-market approval application to US FDA for its second-generation minimally invasive glaucoma surgery (MIGS) *iStent* device used for treating glaucoma, the second-leading cause of blindness.

San Clemente, Calif.-based ophthalmic medical technology company *Glaukos Corp.* announced on Dec. 27 it has submitted a pre-market approval application to US FDA for its minimally invasive glaucoma surgery (MIGS) *iStent inject* device used for treating glaucoma.

Glaukos pioneered MIGS devices, which are among the fastest-growing technologies for treating refractive mild to moderate glaucoma by reducing intraocular pressure, or IOP, and the progression of glaucoma. Up until last year, it was also the only company in the US with an FDA-approved MIGS device. (Also see "*Glaukos' Micro-Bypass Stents Work As First-Line Glaucoma Therapy*" - Medtech Insight, 26 Sep, 2016.) and (Also see "*Glaukos rolls on with direct sales conversion for new-gen iStent*" - Medtech Insight, 10 Feb, 2016.)

Glaukos, however, will be facing increased competition from start-ups and big players such as *Allergan Inc.* and *Alcon Inc.*, which have acquired MIGS technologies to get a piece of the action in this growing market segment. (Also see "*Alcon Puts Money Where Mouth Is With Glaucoma Device Buy* " - Scrip, 22 Feb, 2016.)

The iStent inject is part of the company's second-generation pipeline and features two stents that are pre-loaded into an auto-injection system. Each iStent inject is about one-third the size of the first generation iStent and is expected to be easier to implant by surgeons.

"The iStent inject represents the first in a series of five new products we are expecting to introduce over the next five years, culminating in what we believe will be the industry's broadest portfolio of technologies designed to address the full range of glaucoma disease states and progression," says Thomas Burns, president and CEO of Glaukos.

"This PMA submission marks a significant milestone for Glaukos as we continue to deliver our deep pipeline of novel glaucoma surgical devices and sustained pharmaceuticals," Glaukos President and CEO Thomas Burns said in a release. "The iStent inject represents the first in a series of five new products we are expecting to introduce over the next five years, culminating in what we believe will be the industry's broadest portfolio of technologies designed to address the full range of glaucoma disease states and progression."

Following the announcement, Wells Fargo Senior Analyst Larry Biegelsen said in his Dec. 27 analysis that he expects the US launch of the iStent inject, projected for the second half of 2018, "to reaccelerate top-line growth."

Biegelsen wrote that he expects Glaukos' worldwide sales to grow by more than 9.2% and climb to more than 21.4% in 2019. That is following iStent inject's expected FDA approval and US market launch in 2018.

In a multicenter, controlled pivotal trial of 505 patients who were randomized to receive either cataract surgery alone or cataract surgery with the iStent inject, the iStent inject met its primary efficacy endpoint, which was a 20% or greater reduction in IOP from baseline at 24 months, Glaukos said. The company plans to release efficacy and safety data in the first half of 2018.

Biegelsen believes the second-generation device offers clinicians benefits of increased efficacy over the first-gen iStent device, and increased ease of use.

James Murphy, a glaucoma specialist at the Eye Center of Southern Connecticut in New Haven, agreed. Murphy, who has

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been using the first-gen iStent technology since it was introduced in the US in 2012, told *Medtech Insight* that he is excited about the second-generation device, which he believes will be easier to use. And with that, the door will open for its use by comprehensive ophthalmologists.

The iStent inject relies on the same fluidic method of action as the company's first-generation iStent and has been shown to lower IOP in adult cataract patients with mild-to-moderate open-angle glaucoma.

The device is currently approved for use in the European Union, Armenia, Australia, Brazil, Canada, Hong Kong, Singapore and South Africa.

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The rising aging population and ever-increasing incidences of glaucoma and cataract are clearing a bright path for the ophthalmic surgical products market, which is expected to reach $9.4bn by 2021, a CAGR of 4.6% from 2016. *Meddevicetracker* expects that continued innovation in minimally invasive technologies and next-generation surgical systems, developed by giants like Alcon and smaller rivals, will address the...

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