For immediate release

Positive outcomes for iSTAR Medical's MIGS MINIject shown in trials of over 130 glaucoma patients

Pooled data confirm excellent safety and efficacy profile with very low rate of reintervention

WAVRE, Belgium — 29 September 2020: iSTAR Medical, a medtech company developing minimally invasive ophthalmic implants for powerful, safe and enduring treatment of patients with glaucoma, announced today that its micro-invasive glaucoma surgery (MIGS) device MINIject™ showed consistently positive safety and efficacy outcomes in a larger patient population from ongoing trials. The pooled analysis reviewed data from over 130 patients implanted with MINIject into the supraciliary space in stand-alone procedures across 11 trial sites in Europe, the Americas and Asia.

The final two-year data from the STAR-I trial and the six-month follow-up data from the STAR-II European trial, which are comprised in the pooled analysis, will both be presented at the upcoming European Society of Cataract and Refractive Surgery (ESCRS) meeting on October 2-4. The six-month primary endpoint results from the STAR-II trial of MINIject have recently been published in the peer-reviewed *Journal of Glaucoma*, the official publication of the World Glaucoma Association.

Safety results

According to the pooled data analysis, only 5 percent of patients implanted with MINIject have required secondary glaucoma surgery to date. Considering that a third of patients have already completed 18 and 24-month follow-up, the reintervention rate is very low compared to standalone trials for other MIGS devices.[1,2,3,4] Minimising the number of repeat surgical interventions for glaucoma while preventing disease progression may help improve visual function and quality of life at a sustainable personal and financial cost, which are key patient management goals long-term.[5]

Moreover, mean central corneal endothelial cell density (ECD) loss at six months was only 2 percent and there was no occurrence of ECD loss greater than 30 percent in patients analysed per protocol from all MINIject trials followed-up at six months. In patients from the STAR-I trial, which concluded at two-years, mean ECD loss remained low (5 percent), with no patient having ECD loss greater than 30 percent at study completion. High ECD loss levels can cause corneal edema and loss of transparency, which disrupt vision. MINIject's low ECD loss outcomes are very promising for a MIGS device.[7,8]

"For optimal treatment of my glaucoma patient over the longer-term, I need a procedure that works the first time, delays more invasive surgery and maintains conjunctival health," stated Professor Julián García-Feijoó from Hospital Clinico San Carlos, Complutense University, Madrid (Spain) and a STAR-II study investigator. "The data available so far suggest that MINIject works

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[1] García-Feijoo, J et al. "Supraciliary Microstent in Refractory Open-Angle Glaucoma: Two-Year Outcomes from the DUETTE Trial." J Ocul Pharmacol Ther. 2018 Vol 34(7):538-542

2 Grover D.S. et al. "Performance and Safety of a New Ab Interno Gelatin Stent in Refractory Glaucoma at 12 Months." Am. J. Ophthalmol. 2017 Nov;183(25-36)

3 Voskanyan L et al. "Prospective, unmasked evaluation of the iStent® inject system for open-angle glaucoma: synergy trial." Adv Ther 2014 Feb;31(2): 189-201

4 I.I.K.Ahmed et al. "A Prospective Randomized Trial Comparing Hydrus and iStent Microinvasive Glaucoma Surgery Implants for Standalone Treatment of Open-Angle Glaucoma: The COMPARE Study." Ophthalmology 2020;127:52-61.

5 European Glaucoma Society Terminology and Guidelines for Glaucoma, 4th Edition: British Journal of Ophthalmology. 2017;101:1-195 https://bjo.bmj.com/content/101/5/73

6 Glaucoma Surgical Device Market Report, published by Market Scope, August 2020. https://www.market-scope.com/pages/reports/202/2020-glaucoma-surgical-device-market-report-a-global-analysis-for-2019-to-2025-august-2020

7 HORIZON data submitted to FDA: https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170034B.pdf

8 Lass J.H. et al. "Corneal Endothelial Cell Loss and Morphometric Changes 5 Years after Phacoemulsification with or without CyPass Micro-Stent." Am J Ophthalmol 2019;208:211–218.

effectively, may help prevent risks, and improves overall patient management compared with other surgical treatments," he added. "The implant adapts well to the anterior segment anatomy and scleral curvature so there is no contact with the corneal endothelium. At 6 months, mean ECD loss was just 2%; these results are promising, but have to be confirmed in the long-term."

Efficacy data
Pooled data from patients implanted with MINIject in the STAR-I and STAR-II trials showed a mean IOP reduction of 40 percent and mean IOP 14.5±5.4 mm Hg at six months, from 23.9±3.4 mm Hg at trial start ($p<0.0001$). Eye pressure is considered normal up to 21 mm Hg. In addition, a remarkable 70 percent of patients became and remained medication-free six months after intervention, from a mean 2.4±1.1 medications used per patient before trial start.

Two-year data from the STAR-I trial showed that mean IOP remained low (13.8±3.5 mm Hg) and nearly 50 percent of patients remained medication-free.

"The outstanding results in IOP and medication reduction observed in patients treated with MINIject across trials are unprecedented for a MIGS device, considering that they purely reflect the outcomes from MINIject use, without concomitant cataract surgery," stated Doctor I. Paul Singh, glaucoma specialist, President of The Eye Centers of Racine & Kenosha (Wisconsin USA), and one of the implanting surgeons in the MINIject trials.

"We are analysing pooled data from all ongoing MINIject trials to outline data consistency in a larger patient population," explained iSTAR Medical CEO, Michel Vanbrabant. "The very promising efficacy, safety and longer-term results in the supraciliary space to date boost confidence in MINIject's potential to revolutionise treatment for patients with glaucoma," he concluded.

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For more information
Katherin Awad
iSTAR Medical
news@istarmed.com
+32 10 77 16 54

About iSTAR Medical
iSTAR Medical SA is a medtech company developing minimally invasive ophthalmic implants for powerful, safe and enduring treatment of patients with glaucoma. iSTAR Medical has exclusive rights for ophthalmic use of the STAR® biomaterial developed by the University of Washington, Seattle (USA). STAR® has outstanding anti-fibrotic and anti-inflammatory properties and a unique porous structure that enhances natural fluid outflow. iSTAR Medical was founded in 2011 and is headquartered in Wavre, Belgium.

About MINIject™
MINIject is iSTAR Medical's revolutionary Micro-Invasive Glaucoma Surgery (MIGS) device for patients with primary open-angle glaucoma. MINIject combines the unique porous structure of the proprietary STAR® material with the power offered by the supraciliary space. As a result, it is designed to enhance natural fluid outflow while bio-integrating with surrounding tissue, reducing IOP and need for medication, as well as inflammation, fibrosis and complications.

About Glaucoma
Glaucoma is a progressive disease and the second leading cause of adult blindness,[5] affecting over 100 million people globally.[5] IOP reduction, through medication or surgery, helps delay disease progression.[5] Medication is generally the first line treatment, but the progressive addition of multiple drops can burden patients with side effects, difficulty with compliance and costs.[5,6] Invasive surgery can present risks and irreversible complications for patients.[5,6] The enhanced safety profile makes MIGS the most promising and fastest-growing therapy for glaucoma,[6] with MINIject potentially best-in-class for its promising longer-term efficacy and safety profile.