

For immediate release

iSTAR Medical's glaucoma device MINject shows positive one-year results in European trial

Growing body of evidence confirms MINject is safe and effective with results sustained over time

WAVRE, Belgium — 16 November 2020: [iSTAR Medical](#), a medtech company developing minimally invasive ophthalmic implants for treatment of patients with glaucoma, today announced positive one-year results from the European STAR-II clinical trial of its micro-invasive glaucoma surgery (MIGS) device, [MINject™](#). The results have been presented at the virtual American Academy of Ophthalmology (AAO) annual meeting, held 13-15 November 2020.

- **Positive one-year results from the STAR-II European trial sustain the remarkable six-month outcomes and are consistent with the STAR-I trial results at one year**
- **Promising MINject data at two years from the STAR-I trial were recently published in the *British Journal of Ophthalmology***
- **Pre-clinical studies of MINject highlighting the anti-fibrotic properties of its STAR® material were recently published in *BMC Biomedical Engineering***

STAR-II results at one year

At one-year follow-up, mean intraocular pressure (IOP) was 15.1 mm Hg, corresponding to a 38 percent reduction from medicated baseline IOP. Moreover, 45 percent of patients did not require any IOP-lowering medication one year after intervention (from a mean of 2.9 medications at baseline). In a *post-hoc* analysis in medication-free patients, IOP was reduced further by 46 percent to 13.1 mm Hg at one year. There were no significant overall safety issues, nor concerns with corneal health.

“The STAR-II results at one year confirm MINject is a remarkably effective treatment option for patients with glaucoma. It is encouraging to see that the positive six-month results have been sustained at one year,” explained Professor Julián García-Feijoó from Hospital Clinico San Carlos, Complutense University, Madrid (Spain) and a STAR-II study investigator, who presented the data at AAO.

The STAR-II trial enrolled 29 patients with open-angle glaucoma in eight centres in France, Germany and Spain. Patients will be followed for two years post-intervention.

Promising longer-term data

The one-year STAR-II data are consistent with the one-year outcomes from the first MINject trial, STAR-I. The final results from STAR-I, which enrolled 25 patients followed-up for two years, have just been published in the peer-reviewed [British Journal of Ophthalmology \(BJO\)](#).¹ Two year results of the STAR-I trial show sustained IOP reduction and no issues with corneal health.

“With STAR-I and STAR-II trial results consistent at one year, we may expect them to be similarly comparable at two years. As an innovative standalone MIGS device, MINject certainly has potential; we look forward to having a treatment option in the supraciliary space once more,”

¹ Denis P, Hirneiß C, Durr GM, et al. Two-year outcomes of the MINject drainage system for uncontrolled glaucoma from the STAR-I first-in-human trial. *British Journal of Ophthalmology*. Published Online First: 03 October 2020. <https://doi.org/10.1136/bjophthalmol-2020-316888>

stated Dr Ike Ahmed, senior author of the BJO article and a STAR-I trial investigator, from University of Toronto, Canada.

Bio-integration and anti-fibrotic properties

The sustained performance shown by MINject in patients may be connected to the bio-integration and anti-fibrotic properties of its STAR® material, according to pre-clinical trial results just published in the peer-reviewed journal [BMC Biomedical Engineering](#).²

Studies conducted in rabbits showed that MINject bio-integrates with surrounding tissue. The STAR material's porous structure gets colonised by neighbouring "healthy" cells that do not block the flow of aqueous humor through the device. Following this colonisation, no fibrosis, nor implant encapsulation, nor dense connective tissue obstructing drainage channels were observed, even though this animal model is known for its aggressive inflammatory response. Therefore, MINject's bio-integration and anti-fibrotic properties may help preserve its permeability and enhance long-term outflow, resulting in enduring IOP reduction.

"The consistently positive results from MINject trials are gaining strong attention from the scientific and medical communities for its potential to improve outcomes for patients with glaucoma," explained iSTAR Medical CEO, Michel Vanbrabant. "Our technology enables a new, truly bio-compatible approach for powerful, safe and enduring treatment, which we are eager to offer to patients soon," he concluded.

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For more information

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About iSTAR Medical

iSTAR Medical SA is a medtech company developing minimally invasive ophthalmic implants for treatment of patients with glaucoma. iSTAR Medical has exclusive rights for ophthalmic use of the STAR® material 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. For more information: www.istarmed.com

About MINject™

MINject is iSTAR Medical's revolutionary MIGS device for patients with primary open-angle glaucoma. MINject combines the unique porous structure of its proprietary STAR material with the power offered by the supraciliary space. As a result, it is designed to enhance natural fluid outflow, reducing IOP and the need for medication, while bio-integrating with surrounding tissue, limiting inflammation, fibrosis and subsequent complications.

About Glaucoma

[Glaucoma](#) is a progressive disease and the second leading cause of adult blindness,³ affecting over 100 million people globally.³ IOP reduction, through medication or surgery, helps delay disease progression.³ Medication is generally the first line treatment, but the progressive addition of multiple drops can burden patients with side effects, compliance challenges and costs.^{3,4} Invasive surgery can present risks and irreversible complications.^{3,4} MIGS is the most promising and fastest-growing glaucoma therapy due to its enhanced safety profile.⁴ MINject is potentially best-in-class for its promising long-term efficacy and safety.

² Grierson I, Minckler D, Rippey MK, et al. A novel suprachoroidal microinvasive glaucoma implant: in vivo biocompatibility and biointegration. *BMC biomed eng* 2, 10 (2020). <https://doi.org/10.1186/s42490-020-00045-1>

³ 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>

⁴ 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>