

## iSTAR Medical's MINject shows consistent results at 18-month follow-up in first-in-human trial (STAR-I)

**WAVRE, Belgium — 10 July 2019:** iSTAR Medical SA, a private medical device company developing novel ophthalmic implants for the treatment of glaucoma, today announced consistent 18-month results of the first-in-human, micro-invasive glaucoma surgery (MIGS) STAR-I trial for the MINject™ device in a standalone setting. These results confirm the stability and sustained performance of MINject beyond the first year.

The STAR-I trial demonstrated that the implantation of MINject resulted in a mean pressure of 15.0 mmHg at 18-months, consistent with results reported at 1 year, and at a level expected to reduce the progression of glaucoma. In addition, almost two-thirds of the patients were able to stop taking their eye drops. These results confirm that the safety and effectiveness of MINject is sustained over time, with minimal patient-management required.

**Dr Ike Ahmed, University of Toronto, Ontario, Canada**, who performed some of the first MINject procedures in the STAR-I trial, commented: *"The stable pressure between 1 year and 18 months is reassuring as to the sustained performance of MINject over time. MINject's STAR material and its use in the supraciliary space is a promising combination."*

Early six-month results of MINject in the STAR-I trial were [published](#) online in June in Ophthalmology-Glaucoma, the journal of the American Glaucoma Society (AGS). The 18-month results of MINject will be presented in detail on Friday, 13 September 2019, during Glaucoma Day at the ESCRS congress in Paris, France.

**Michel Vanbrabant, CEO of iSTAR Medical**, added: *"iSTAR Medical is setting new frontiers in MIGS treatment of glaucoma. We are thrilled to see MINject's powerful and reliable efficacy in a standalone procedure sustained over time, without a trade-off between safety and efficacy, and without requiring invasive follow-up procedures or surgeries. We look forward to bringing this therapeutic option in the supraciliary space to market for glaucoma patients."*

iSTAR Medical has also completed enrolment in STAR-II, a pivotal European trial. The results of STAR-II will support the company's application for CE-Marking for MINject, which is expected in 2020.

[http://www.istarmed.com/wp-content/uploads/2019/07/iSTAR\\_MINject-FIH-trial-18-month-results-EN.pdf](http://www.istarmed.com/wp-content/uploads/2019/07/iSTAR_MINject-FIH-trial-18-month-results-EN.pdf)

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## About MINject

iSTAR Medical's MIGS device, MINject™, provides a safe, effective and sustainable solution to significantly reduce IOP by enhancing aqueous humour outflow from the anterior chamber to the supraciliary space. MINject takes a new approach to drainage which represents a paradigm shift. Unlike other technologies, MINject uses the innovative STAR® material, a soft and flexible, medical-grade silicone with a micro-porous, multi-channel geometry. and is implanted with a very small part of the device remaining in the anterior chamber. The proprietary STAR material has anti-fibrotic properties, which minimise scarring and maintain implant performance, improving long-term outcomes compared with other MIGS solutions. MINject has been partially funded by the Walloon Region, Belgium.

## About the STAR-I trial

The STAR-I trial is a prospective, open, international, multi-centre study in which MINject was implanted in 25 patients with mild-to-moderate, primary open angle glaucoma uncontrolled by topical hypotensive medication. The aim of the study is to assess the safety and performance of the MINject device measured by IOP reduction under medication from baseline to six months, with follow-up to two years post-surgery.

## About iSTAR Medical SA

iSTAR Medical SA, headquartered in Wavre, Belgium, is a private, clinical-stage, medical technology company focused on the development of novel ophthalmic implants for glaucoma.

Glaucoma is the second leading cause of adult blindness globally, affecting more than 92 million people worldwide. Micro-invasive glaucoma surgery (MIGS) is the most promising and fastest-growing therapeutic option in the treatment of glaucoma. iSTAR has exclusive rights to the STAR® biomaterial from the University of Washington in Seattle (USA) for ophthalmic use. This provides the foundation for the development of MINject™, designed to be a best-in-class MIGS device. The fast-growing glaucoma drainage device market is expected to reach \$1bn worldwide by 2020.

iSTAR Medical's management team and board have a successful track record in end-to-end product development, with proven clinical, regulatory and market access capabilities. The company is backed by specialised institutional and private investors. For more information, please go to [www.istarmed.com](http://www.istarmed.com)

## Sources

1. Market research published by Market Scope, August 2018.