

For immediate release

iSTAR Medical shows initial positive progress of US STAR-V trial for MINInject

- *Pivotal trial of MINInject, STAR-V, now initiated in 13 sites across the US*
- *Positive feedback from world-leading glaucoma surgeons involved in the trial*
- *MINInject is the only commercially available MIGS device targeting the supraciliary space. Commercial rollout continues following European approval in 2021*

WAVRE, Belgium — 12 January 2022: [iSTAR Medical](#), a medtech company delivering breakthrough eye care solutions to patients, today announced initial positive progress of MINInject™ in its US STAR-V trial. MINInject is a potentially best-in-class minimally-invasive glaucoma surgery (MIGS) implant and the only commercially available supraciliary MIGS device. The trial is now initiated in 13 sites across the US with positive feedback on initial implantations from world-leading glaucoma surgeons.

MINInject has demonstrated meaningful and enduring intraocular pressure (IOP) reduction, combined with a favorable safety profile, in completed and ongoing trials conducted in Europe, the Americas and Asia in over 150 patients so far.

The [STAR-V](#) trial is a US FDA-approved pivotal study assessing the safety and efficacy of MINInject in over 350 patients with primary open-angle glaucoma across the US, Canada and Europe. Following the trial's [FDA IDE approval](#) in 2021, patient enrollment has been progressing as planned.

Glaucoma specialist Dr Steven D. Vold, from Vold Vision in Fayetteville, AR (USA), a long-standing contributor to ophthalmic device development and STAR-V trial investigator commented: *“There is significant untapped potential in targeting the supraciliary space when leveraging MIGS to treat glaucoma, and MINInject enables this to be captured. iSTAR Medical’s approach uses its unique silicone micropore tissue friendly STAR material that enables biointegration. The supraciliary space has previously been demonstrated to be one of the most efficacious targets, and I am excited at the prospect of having a new MIGS approach with such strong potential to offer my patients.”*

Dr Brian E. Flowers, a glaucoma specialist at Ophthalmology Associates at Fort Worth, TX (USA), and one of the investigators in STAR-V, said: *“MINInject’s highly biocompatible anti-fibrotic technology enables safe and meaningful IOP reduction for patients, without compromising corneal health. Additionally, it doesn’t require a bleb, reducing post-implantation patient management and potential complications. Overall, based on my implantations to date, I am encouraged by MINInject’s potential to be a game-changing MIGS device in the stand alone setting to improve disease management and quality of life in glaucoma patients.”*

Dr. William J. Flynn, MD, from Eye Associates Research in San Antonio, TX (USA), expressed: *“Due to its promising powerful efficacy and safety, MINInject may open the door to treating a much larger patient population who previously couldn’t be treated by other MIGS devices. I am excited to be part of this trial and based on my positive experience thus far, I am optimistic for MINInject to be a valuable addition to our glaucoma treatment armamentarium.”*

Michel Vanbrabant, CEO of iSTAR Medical, commented: *“Following last year’s success with the approval of MINInject in Europe, we are excited to be progressing so positively in our pivotal approval trial in the United States. We remain very encouraged by the strong feedback from*

clinicians so far, and we are confident that our STAR-V trial will build on the safety and powerful efficacy outcomes demonstrated by MINJect in the STAR-I to STAR-IV trials.”

- Ends –

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About iSTAR Medical

iSTAR Medical is committed to delivering breakthrough eye care solutions. Our most advanced product, MINJect, is approved in Europe for the treatment of open-angle glaucoma – the leading cause of irreversible blindness¹ – and we are aiming to seek market approval in the US. We believe MINJect’s unique tissue-integrating capabilities unlock a safer, and more effective option for patients. We are building an exceptional team and pipeline of best-in-class products such as MINJect to establish new treatment paradigms in eye care conditions with the highest patient needs. For more information, please visit: www.istarmed.com

About MINJect™

[MINJect](#) is iSTAR Medical’s innovative 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 intraocular pressure (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 affecting over 100 million people globally, of which primary open-angle glaucoma is the most common form.^{1,2} 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.^{2,3} Invasive surgery can present risks with irreversible complications and often requires long-term patient management.^{2,3} MIGS is the most promising and fastest-growing glaucoma therapy due to its enhanced safety profile.² MINJect is potentially best-in-class for its promising long-term efficacy and safety.

¹ Jonas JB, Aung T, Bourne RR et al. "Glaucoma". Lancet 2017; 390: 2083–93

² Market Scope, "2021 Glaucoma Surgical Device Market Report", July 2021. <https://www.market-scope.com/pages/reports/267/2021-glaucoma-surgical-device-market-report>

³"European Glaucoma Society Terminology and Guidelines for Glaucoma", 4th Edition: *British Journal of Ophthalmology*. 2017;101:1-195 <https://bj.o.bmj.com/content/101/5/73>