

For immediate release

**iSTAR Medical receives U.S. FDA approval to start pivotal trial for
MINIject in glaucoma patients**

World-leading surgeons to join iSTAR Medical's STAR-V study

WAVRE, Belgium — 15 July 2021: [iSTAR Medical](#), a med-tech company developing minimally-invasive implants for glaucoma surgery (MIGS), announced today that the U.S. Food and Drug Administration (FDA) granted it Investigational Device Exemption (IDE) to start a pivotal trial with [MINIject™](#). The STAR-V study will investigate MINIject™ in over 350 patients with primary open angle glaucoma. World-leading glaucoma surgeons in the US, Canada and Europe will join the trial.

The STAR-V trial evaluates MINIject's efficacy by the mean reduction in eye pressure, as well as the proportion of patients achieving at least a 20 percent reduction in eye pressure. This study will report on safety and efficacy of MINIject alone, in a procedure not combined with simultaneous cataract surgery. Key study findings will become available when all patients have completed 2 years in the study. Patients will also be followed to evaluate long-term benefits and tolerability of MINIject™ in the treatment of mild to moderate glaucoma.

Dr. Brian E. Flowers, a glaucoma specialist at Ophthalmology Associates of Fort Worth, TX, USA said *"On behalf of the investigators, I would like to share our excitement to start the STAR-V trial. The supraciliary space of the eye is a natural outflow pathway which has demonstrated great promise. There is the potential to deliver increased efficacy in lowering eye pressure for our patients in a less invasive fashion. Access to an effective pressure lowering device that is used in a standalone procedure will enable us to offer treatment to many more glaucoma patients with a minimally-invasive treatment option."*

Michel Vanbrabant, CEO of iSTAR Medical, commented *"We are very pleased that the FDA has granted us approval to bring this innovative technology to North American patients suffering from primary open angle glaucoma in the STAR-V trial. Results from clinical trials in over 130 patients in Europe, Asia and Latin America have consistently demonstrated that MINIject™ maintains a positive safety profile, and delivers a significant reduction of pressure thanks to our proprietary STAR material and the power of the supraciliary space."*

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For more information

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About iSTAR Medical

iSTAR Medical SA is a private med-tech company developing minimally invasive ophthalmic implants for the treatment of glaucoma patients. 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. www.istarmed.com

About MINIject™

[MINIject](#) is iSTAR Medical's revolutionary MIGS device for patients with primary open-angle glaucoma. MINIject 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 and the second leading cause of adult blindness,¹ affecting over 100 million people globally.² IOP reduction, through medication or surgery, helps delay disease progression.¹ Medication is generally the first line treatment, but the progressive addition of multiple drops can burden patients with side effects, compliance challenges and costs.^{1,2} Invasive surgery can present risks with irreversible complications.^{1,2} MIGS is the most promising and fastest-growing glaucoma therapy due to its enhanced safety profile.² MINIject is potentially best-in-class for its promising long-term efficacy and safety.

¹ "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>

² "Market Scope Glaucoma Surgical Device Market Report", 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>