iSTAR Medical receives European market approval for glaucoma implant MINIject

- *The only commercially available, minimally invasive supraciliary device for glaucoma now approved*
- *First commercial implantations of MINIject successfully carried out by world-leading ophthalmologist Prof. Dr. Burkhard Dick at the University Eye Hospital Bochum, Germany*
- *European launch represents pivotal milestone in iSTAR Medical's commercial strategy to bring MINIject to patients globally*

WAVRE, Belgium — 17 November 2021: iSTAR Medical, a medtech company pioneering novel minimally-invasive implants for glaucoma surgery (MIGS), today announced that its breakthrough MIGS device, MINIject™, has been approved in Europe for open-angle glaucoma patients. MINIject enables more patients to be effectively treated with MIGS because of its powerful and sustained performance combined with an excellent safety profile.

Glaucoma is the leading cause of irreversible blindness affecting around 100 million people worldwide.[1,2] MIGS represents the most promising and fastest-growing glaucoma therapy, due to its enhanced safety profile compared to traditional surgery. Data reported to date by iSTAR Medical across four trials in over 150 patients, consistently show that MINIject demonstrates a balance of powerful and sustained intra-ocular pressure (IOP) reduction with a positive safety profile.

MINIject's powerful efficacy and safety make it optimal for treatment in a broader glaucoma population, meaning flexibility for use in a greater number of procedures. iSTAR Medical is now rolling out MINIject commercially in select regions across Europe and is delighted that its first commercial implantations have already taken place in Germany.

Michel Vanbrabant, CEO of iSTAR Medical, commented: "*With today's European approval, MINIject becomes the only commercially available MIGS device targeting the supraciliary space as a natural outflow pathway for IOP reduction. This is a major milestone for iSTAR Medical and our mission to bring truly next-generation MIGS devices to the glaucoma community. I want to thank our team, our investors, and our medical partners for their continued belief in a safer and better way to manage glaucoma by targeting the supraciliary space, with an implant powered by our proprietary STAR® material.*"

[1] 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

Positive two-year results from iSTAR Medical's STAR-II European trial were recently presented at the 125th American Academy of Ophthalmology (AAO) meeting in New Orleans, LA (USA) demonstrating a sustained powerful efficacy and safety outcome in patients with open-angle glaucoma, consistent with all MINIject trial outcomes to date.

Professor Dr. Burkhard Dick, Head of the Department of Ophthalmology at University Eye Hospital Bochum, Germany, and one of the MINIject STAR-II trial investigators, treated the first patient with MINIject after European approval. He commented: *"I'm very pleased that I'm now able to offer the MINIject supraciliary device as a treatment option to my mild-to-moderate glaucoma patients, the first of which was treated successfully today,"* he said. *"Based on results so far, MINIject may open up new treatment paradigms for patients with glaucoma across Europe."*

David Stocker, VP Sales & Marketing at iSTAR Medical added: *"The launch of our first product in Europe sets iSTAR Medical on a very promising trajectory for future value generation. With its unique product characteristics, MINIject has the potential to gain a significant share of the growing wider market for glaucoma treatments and amongst its peers in the MIGS segment. Our ambition is to make this novel MIGS solution available to a broad patient community and grow the organisation, our network and our international footprint to meet the size of the opportunity."*

Furthermore, MINIject is currently being investigated in iSTAR Medical's pivotal STAR-V study, which was approved by the United States Food and Drug Administration (FDA) in July 2021, the results of which will be instrumental to gain commercial access for MINIject in the US market. The study will enrol over 350 patients with primary open-angle glaucoma.

- Ends -

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About iSTAR Medical
iSTAR Medical is committed to delivering breakthrough eye care solutions. Our most advanced product, MINIject, is approved in Europe for the treatment of open-angle glaucoma – the leading cause of irreversible blindness[2] – and is progressing towards market approval in the US. MINIject'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 MINIject to establish new treatment paradigms in eye care conditions with the highest patient needs. For more information, please visit: 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 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

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

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.[1,3] Invasive surgery can present risks with irreversible complications.[1,3] MIGS is the most promising and fastest-growing glaucoma therapy due to its enhanced safety profile.[1] MINIject is potentially best-in-class for its promising long-term efficacy and safety.

[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