iSTAR Medical's MINIject maintains exceptional results in first-in-human trial one year post-surgery (STAR-I)

WAVRE, Belgium — 19 December 2018: iSTAR Medical SA, a private medical device company developing novel ophthalmic implants for the treatment of glaucoma, today announced exceptional one-year results of the first-in-human, micro-invasive glaucoma surgery (MIGS) STAR-I trial, for the MINIject™ device in a standalone setting. Results continue to show that MINIject is safe and highly effective in achieving significant intraocular pressure (IOP) reduction, as well as easing medication burden in glaucoma patients.

The STAR-I trial demonstrated that the implantation of MINIject resulted in an average 32.6% IOP reduction to a mean of 15.6 mmHg at one year. In addition, 75% of patients were able to discontinue topical medication usage and remained medication-free at one year. There were no serious ocular adverse events and no patient required subsequent glaucoma surgery.

The STAR-I trial is a prospective, open, international, multi-centre study in which MINIject 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 MINIject device measured by IOP reduction under medication from baseline to six months, with follow-up to two years post-surgery.

Dr Ike Ahmed, University of Toronto, Ontario, Canada, performed some of the first MINIject procedures in the STAR-I trial. He commented: *"The early performance of MINIject in providing significant pressure reduction in a standalone procedure, with 75% patients still medication-free and excellent safety at 1-year follow-up, has the potential to make a very real impact on improving quality-of-life for patients."*

The MINIject supraciliary device is made of a soft and flexible, micro-porous material, and is implanted with a very small part of the device remaining in the anterior chamber. In the STAR-I study, endothelial cell density (ECD) results post-MINIject implantation showed minimal corneal cell loss compared with baseline at one-year follow-up (mean change of -2%).

Dr Steven Vold, Ophthalmologist at Vold Vision, Arkansas, USA, has extensive experience implanting supraciliary MIGS devices. He said: *"It is reassuring to see that after implantation with MINIject there was minimal change in mean ECD between baseline and one year. These efficacy and safety results are encouraging, and we look forward to having MINIject available for widespread use for our glaucoma patients."*

Publication of these results in a leading medical journal is expected in 2019.

ClinicalTrials.gov identifier: NCT03193736

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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 MINIject™, 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

About MINIject

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

Sources

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