iSTAR Medical's MINIject delivers exceptional 6-month results in first-in-human trial

WAVRE, Belgium — 16 May 2018: iSTAR Medical SA, a private medical device company developing novel ophthalmic implants for the treatment of glaucoma, today announced exceptional six-month results of their first-in-human (FIH) micro-invasive glaucoma surgery (MIGS) trial for the MINIject™ device in a standalone setting. Results show MINIject to be safe and highly effective in achieving significant intraocular pressure (IOP) reduction in glaucoma patients.

The trial showed that the implantation of MINIject resulted in an average 39% IOP reduction to a mean of 14.2 mmHg at six months. In addition, 87.5% of patients were able to discontinue topical medication usage and remained medication-free at six months. There were no serious ocular adverse events.

The FIH trial is a prospective, open, international, multi-centre study in which a 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. Subsequent safety and performance will be measured up to two years post-surgery. The investigators and performing surgeons include Dr Ike Ahmed (Toronto, Canada), Dr Ernesto Calvo (Panama City, Panama), Prof. Philippe Denis (Lyon, France), Prof. Christoph Hirneiss (Munich, Germany) and Dr Anita Kamarthy (Hyderabad, India). Adverse events were assessed by an independent Safety Monitoring Committee (SMC).

iSTAR Medical's MINIject device 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 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 over time.

Prof. Philippe Denis, Croix-Rousse Hospital, Lyon, France, was involved in the development of MINIject. He said: *"We are very pleased with the safety results for this supraciliary procedure. There were no implant migrations. MINIject has been well-designed and the low number of adverse events is encouraging."*

Dr Ike Ahmed, University of Toronto, Ontario, Canada, performed some of the first MINIject procedures in the trial. He commented: *"These early results show a combination of exceptional efficacy, safety for patients, and device ease-of-use, which is very promising."*

Glaucoma is the second leading cause of blindness globally according to the World Health Organisation, affecting over 80 million people. About 2.5 million people worldwide are blind due to glaucoma. MIGS is the most promising and fastest-growing therapeutic option in the treatment of glaucoma.

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. 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, which is 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

Based on the innovative, proprietary STAR® material, iSTAR Medical has developed MINIject™, a MIGS device which is implanted into the supraciliary space. MINIject is designed to deliver enhanced ease-of-use and to improve long-term outcomes compared with other MIGS solutions. The STAR material enhances bio-integration, fluid drainage and conformability to patient anatomy with substantial clinical benefits and an improved patient experience. MINIject has been partially funded by the Walloon Region, Belgium.

Sources

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