iSTAR Medical completes enrolment of first-in-human MIGS trial

Novel MINIject device made from STAR® material successfully implanted in 25 patients

WAVRE, Belgium — 17 October 2017: iSTAR Medical SA, a private medical device company developing novel ophthalmic implants for the treatment of glaucoma, announced today the completion of enrolment in their first-in-human (FIH) micro-invasive glaucoma surgery (MIGS) trial for the MINIject™ device.

The FIH trial is a prospective, open, international, multi-centre study which has recruited 25 patients with mild-to-moderate, open angle glaucoma uncontrolled by topical hypotensive medications for implantation with a MINIject device. Patient enrolment occurred in centres between June and October 2017. The aim of this study is to assess the safety and performance of the MINIject device measured by intra-ocular pressure (IOP) reduction under medication from baseline to 6 months. Subsequent safety and performance will be measured at 12 and 24 months post-surgery.

MIGS is a promising and growing therapeutic option for the treatment of glaucoma, but performance has been limited with early technologies such as stents, mainly due to the fibrotic response generated by surrounding tissues. iSTAR Medical's MINIject device 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 which conforms to the eye anatomy. The porous geometry of the STAR material promotes bio-integration of surrounding tissue into the material which preserves drainage efficacy over time. In addition, anti-fibrotic properties minimise scarring and increase implant durability. MINIject provides a safe, effective and sustainable solution to significantly reduce IOP by enhancing aqueous humour outflow from the anterior chamber to the suprachoroidal space. Implantation is swift and predictable using an injecting mechanism in a single-step procedure.

Dr Ike Ahmed, University of Toronto, Ontario, Canada, performed some of the first MINIject procedures. He commented: *"I am excited to be investigating this novel, next-generation, intuitive MIGS device with the iSTAR Medical team. MINIject offers the potential of an efficacious treatment which may be less fibrotic and thus more sustainable in the long-term."*

Michel Vanbrabrant, CEO of iSTAR Medical, said: *"iSTAR Medical is proud to bring this innovative solution to patients suffering with Glaucoma, a major cause of blindness globally. With our proprietary STAR material, and international support from leading experts, MINIject has the potential to become a best-in-class treatment for Glaucoma. Initial feedback from investigators is encouraging and we look forward to seeing the primary endpoint results next year."*

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 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 suprachoroidal 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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