Next Generation Devices to Treat Glaucoma

Michel Vanbrabant, CEO
OIS@AAO
25 OCT 2018
Key Messages

The next generation MIGS made of anti-fibrotic medical grade silicone STAR material

iSTAR Medical
- Private VC-backed company based in Belgium
- Lead product MINIject™ completed enrolment of First-In-Human clinical trials

MINIject
- Easy to implant in supra-ciliary space
- Anti-fibrotic, soft, conforming to eye shape
- Safe
- Significant and sustained performance
- Low post-operative patient management
MINIject

The next generation MIGS made of anti-fibrotic medical grade silicone STAR material
The STAR® anti-fibrotic material
Rabbit Study, Supra-ciliary Placement – 6m Follow Up

Exceptional Biointegration

of the device with surrounding tissue colonizing the porous structure while preserving in vivo drainage efficacy

No Encapsulation

observed as shown by the absence of a continuous surrounding fibrous capsule, nor continuous macrophage, nor a continuous fibroblast layer

Source:
Prof. Nathalie Collignon (CHU of Liège, Liège, Belgium); In-vivo: CER Groupe (Marloie, Belgium); Histology: GIGA-ULg Immunohistology Platform (University of Liège, Liège, Belgium). March 2013.
Global top leading experts advising company at each step of its progression.
Prospective, Open, Multi-centre Study

- Open angle glaucoma uncontrolled by topical hypotensive medication
- **25 patients**
- 2 year follow-up
- Endpoints:
  - Reduction in IOP
  - Reduction in meds
  - Success rate
  - Safety

**Status:** Primary Endpoint Achieved

Performing surgeons
- Ike Ahmed, MD, Toronto, Canada
- Philippe Denis, MD, Lyon, France
- Christoph Hirneiss, MD, Munich, Germany

Study sites
- E. Calvo, MD, Clinica De Orillac Calvo, Panama city, Panama
- K.P. Reddy, MD, MaxiVision Eye Hospital, Hyderabad, India

Safety & Monitoring Committee
- A. G. Jünemann, MD, Rostock University, Rostock, Germany
- R. D. Fechtner, MD, SUNY Upstate Medical University, NY, USA
- R. A. Eiferman, MD, University of Louisville, Louisville, USA

ClinicalTrials.gov id. NCT02272569
Surgery and Safety

**Surgery**
- Simple surgical procedure with easy to use delivery system
  - <5 mins insertion procedure
  - Access <= 2.0mm corneal incision
- Implant precisely delivered to intended location
- No implant migration to-date
- No use of MMC or 5-FU required

**Safety (to-date)**
- No serious adverse events related to the device
- No clinically-relevant changes in mean refraction or visual field testing
- No clinically significant hypotony
- No additional incisional glaucoma surgery required
- No significant change to mean baseline ECD
MINIject Endothelial Cell Density (ECD)

- MINIject’s STAR material (soft silicone) **conforms** to the eye anatomy

- Green mark on implant precisely guides placement to limit portion in AC to **0.5mm**

- Physicians training to include today’s best practices in particular targeting **below Schwalbe’s line** for any supra-ciliary device

- **UBM** and **Specular Microscopy** in all iSTAR studies from First-In-Human
  - **No migration** of implant
  - **No significant change to ECD at 1Y** (central and peripheral)

**After intervention**

**At 6 months**

**UBM** Patient 04-PA01-20
6-month Results at a glance

**Mean Diurnal IOP**

![Graph showing mean diurnal IOP with 23.2 mmHg at baseline and 14.2 mmHg at 6 months, with a -39% reduction.]

**Topical Hypotensive Medication use at 6 months**

- 16% Medicated patients
- 84% Medication-free patients

**Number of Active Ingredients**

- Baseline: 2.0
- 6 mths: 0.3

ClinicalTrials.gov id. NCT02272569
12-month Results at a glance
(Preliminary results: N=19)

Mean Diurnal IOP

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<th>Baseline</th>
<th>12M</th>
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<td>23.1</td>
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<td>15.2</td>
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-33%

Topical Hypotensive Medication at last visit

- 84% Medication-free patients
- 16% Medicated patients

Number of Active Ingredients

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<th>Baseline</th>
<th>12M</th>
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Clinical & Regulatory Path to Market

Legend
- Study
- Approval

Feasibility

2017
- FIH (ISM04)

2018
- FIH (ISM05)

2019
- Stand-alone
- comb.w/cataract

2020
- IDE

21 - 22
- FDA 510K approval by 2022
- CE mark for SA expected by end 2019
Board of Directors and Management Team

Philippe Degive
- Representative of Société Régionale d’Investissement de Wallonie (“SRIW”)
- Current and past board memberships: one Therapeutics, Promethera Biosciences, Ogeda, Cardio Life Research

David Guyer, MD
- Co-Founder & Chairman of Ophthotech Corp.
- Previously: SV Life Sciences. Co-founder of Eyetech Pharmaceuticals, Inc., B.S. from Yale College & M.D. from Johns Hopkins

Max Maginness
- President and co-founder, Healionics Corporation
- Formerly with Siemens Medical, ATL (now Philips Ultrasound) and subsidiaries of CIBA-Geigy managing multiple new product development and technology transfer projects

Marc Nolet de Brauwere
- CEO of PhysIOL (cutting-edge IOLs)
- Current board membership: Bone Therapeutics, Cardiatis, Mymicroinvest, Endo Tools Therapeutics, Biotech Coaching and Aliaxis

Katya Smirnyagina
- Partner, Capricorn Health-Tech Venture Fund
- Formerly with Alta Partners
- Current and past board memberships: Adocia, Confo Therapeutics, Nexstim, Abylnx, Cerenis Therapeutics, Innate Pharma and Kiadis Pharma

Marty Wax, MD
- CMO and Executive VP of R&D at PanOptica, Inc.
- Formerly VP and Head of Discovery Research and Pre-Clinical Sciences at Alcon
- Clinical Professor of Ophthalmology and Visual Sciences at Rutgers Medical School in Newark, N.J.

Michel Lussier, Chairman of the Board
- CEO of Metronom Health, Chairman of Celyad
- Formerly a senior executive with Medtronic and Volcano

Michel Vanbrabant, CEO
- 20+ years of experience in Medical Technology
- Held several international positions at leading MedTech companies including Guidant Inc. (now Boston Scientific) and St.Jude Medical
- Experience in several start-up organisations with a focus on go-to market strategy and implementation

Eugene Smyth, CFO
- 20+ years as head of finance in quoted and privately owned international companies
- Experience with early stage companies, VC investors and M&A
- Formerly with PWC, Medtronic, InControl (acquired by Guidant) and Guidant

Zubair Hussain, Regulatory & Clinical Affairs
- 20+ years experience in Regulatory, Quality, Compliance and Clinical Affairs for Pharmaceutical and Medical Device companies including in Vision care
- Formerly with Pfizer, Alcon, Ipsen

Dan Scherrer, Operations
- 20+ years experience in Operations, Product Development and Supply Chain Management for Medical Device, Food and Electronics.
- Formerly with DePuy Spine (JNJ), Synthes, Biwi

Cecile Roy, Manufacturing
- 7 years of research experience with bio-polymeric products for drug delivery applications
- Co-inventor of the MINject device

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MINiject: Summary

The next generation MIGS made of anti-fibrotic medial grade silicone STAR material

• Positive one year data presented for the first time at OIS

• Safety profile continues to look very promising - ECD side effects not expected due to material properties and proper placement in anterior chamber

• Performance data supports utility and patient acceptance being excellent for the vast majority of mild to moderate glaucoma patients
Thank you!

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