“MIGS”
Minimally Invasive Glaucoma Surgery

Working Definition / Panel Ground Rules
Joint FDA – AGS Meeting

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Alcon Surgical
AMO
AqueSys
Endo-Optiks
Glaukos
Ivantis
Minimally Invasive Glaucoma Surgery

• Evolving space
• No well accepted definition
• Includes a diverse group of “alternative” glaucoma surgeries that are intended to be safer, and induce considerably less tissue disruption than traditional procedures
Surgical Safety and Efficacy

• In general surgical safety and efficacy are related to...
  – Mechanism of IOP reduction
  – Reservoir for aqueous egress
  – Complexity of surgical maneuvers
  – Extent of tissue manipulation
  – Frequency of complications and/or adverse events
MIGS: Reservoir for Aqueous Outflow

MIGS are diverse

• *Best categorized by the recipient reservoir which has significant influence on both safety and efficacy*
  – Schlemm’s canal
  – Suprachoroidal Space
  – Sub-conjunctival Space
Schlemm’s Canal

- Most physiological
- Synergistic with innate outflow pathway
- Mechanism maximizes safety
  - ESVP provides “safety net” barrier, eliminating risk of hypotony
  - Accordingly, efficacy has similar limitations
  - Success dependent on viability of distal outflow system
Suprachoroidal Space

- Less synergistic to innate mechanism
- Hypotony theoretically possible
- No theoretical limitation to efficacy based on resistance of the recipient bed
- Disuse atrophy of physiological system is possible post-operatively
- Greater theoretical risk than canal based procedures
  - Large trials may prove or disprove this premise for a particular device
Subconjunctival Space

• Not synergistic to innate mechanism
• No theoretical barrier to efficacy
• Hypotony theoretically possible
• Disuse atrophy of physiological system possible
• *Extra-scleral* egress introduces risk of endophthalmitis
• Greater theoretical risk than canal based procedures
  – Large trials may prove or disprove this premise for a particular device
Ultimately...

**MIGS classification may need to be “earned”...**

Based on:

- *at least modest efficacy*

and more importantly...

- *an enhanced safety profile as determined by well controlled clinical trials*
Minimally Invasive Glaucoma Surgery - Implantable Devices

*Definition for today’s panel discussions*....

- Intended to lower IOP via an outflow mechanism
- Either ab-interno or ab-externo approach
- Very limited or no scleral dissection
  - *needle or device penetration/perforation of sclera allowed*
  - *procedures involving significant scleral dissection excluded*
- Minimal or no conjunctival manipulation
  - *limited peritomy or small incision allowed*
EXISTING EXAMPLES OF MIGS FOR THIS AFTERNOON’S FDA–AGS PANELS:

**Canal Based**

*Trabecular microbypass stents*

✓ Glaukos iStent
✓ Ivantis Hydrus

**Suprachoroidal Based**

*Ab-interno suprachoroidal stents*

✓ Glaukos iStent Supra
✓ Transcend CyPass

**Sub-conjunctival Based**

*Ab-interno, trans-scleral filtration devices*

✓ AqueSys Xen

*Ab-externo trans-scleral filtration devices*

✓ InnFocus Microshunt
Minimally Invasive Glaucoma Surgery - Implantable Devices

**Definition for today’s panel discussions...**

EXCLUDED FOR TODAY’S FDA-AGS PANEL DISCUSSIONS
(But may be included in other MIGS definitions)

**Canal Based**

**Ab-Interno Trabeculectomy**
- Trabectome – no device implanted

**Ab-Interno Trabeculotomy**
- iScience catheter – no device implanted

**Suprachoroidal Based**

**Ab-externo suprachoroidal stents**
- Solx Gold Shunt – more extensive scleral dissection

**Sub-conjunctival Based**

**Ab-externo trans-scleral filtration devices**
- Alcon ExPress – more extensive scleral dissection
Safety and Efficacy Standards for MIGS

- Safety and efficacy are inexorably linked
- While all procedures should have at least modest efficacy...
  - safer procedures might be held to more modest efficacy standards...
  - while procedures with greater risk may be expected to have greater efficacy
- The indications for each MIGS may differ based on *both* efficacy and safety considerations
Despite the diverse nature of the procedures collectively known as MIGS...

- Panels challenged (as much as possible) to establish uniformity of clinical trials involving MIGS implantable devices:
  - Eligible Patients and Severity Endpoints
  - Safety Endpoints
  - Efficacy Endpoints
Thank-you