Bringing Innovation to Ocular Oncology

FDA Designations
- Orphan Drug Designation 2015
- Fast Track Designation 2017

AU-011
- Novel technology discovered at National Cancer Institute
- Lasker Award 2017

Phase 1b/2
- Safety and Preliminary Efficacy Trial 2018

Commercial Launch

Phase 3
- Phase 3 initiation in 2019
Choroidal melanoma: A substantial unmet medical need

Annual incidence\(^1\)

11,000 patients worldwide

Primary Treatment: Plaque Brachytherapy & Proton Beam Therapy

- Blindness
- Iatrogenic complications
- No survival advantage
- Requires multiple surgeries

High rate of metastases

- Lung (29%)
- Liver (89%)
- Bone (17%)

Mortality rate of up to 92% at 1-2 years after diagnosis of metastases\(^2\)

Approx 30% diagnosed with metastases within 10 years\(^2\)

Untapped rare disease opportunity to treat early stage disease

- Small melanomas and indeterminate lesions: 8,500 patients per year (77%)
- Large melanomas: 700 patients per year (7%)
- Medium melanomas: 1,800 patients per year (16%)

Choroidal Melanoma

- AU-011 First Line Treatment*

*AU-011 is an Investigational Drug and not approved for Choroidal Melanoma

Source:
Clearview 2018 Study Report (40% US, 40% EU, 20% ROW)
AU-011: Designed to revolutionize the treatment paradigm in ocular melanoma

**OFFICE BASED PROCEDURE**

Does not require surgery or radioactivity

**MINIMALLY INVASIVE**

Intravitreal injection and ophthalmic laser activation

**TARGETED THERAPY PRESERVES VISION**

Enables early treatment intervention with vision preservation

**CONCENTRATED MARKET**

100 Ocular Oncologists in the US/EU
Viral like particle bioconjugates (VPB) are delivered by intravitreal injection. VPBs bind specifically to HSPGs on the tumor cell surface (multivalent binding). Irradiation with NIR light.

Ophthalmic laser activates the drug. The light-activated drug disrupts the tumor cell membrane, leading to acute cellular necrosis.

AU-011 Mechanism of Action: acute tumor cellular necrosis upon light activation.

AU-011 is an investigational drug and not approved for choroidal melanoma.
Market Opportunity:
• >$750M worldwide*
• No FDA approved therapy
• Focused call point

Clinical Trial Objectives:
• Local tumor control
• Maintenance of visual acuity

Value Proposition:
• Early treatment of tumors without the vision loss associated with current radioactive-based methods
• Office-based non-surgical and non-radioactive procedure

*Clearview 2018 Study Report
**Orphan and Fast Track Designation with FDA
Phase 1b/2 study design

**Single Dose Cohorts (Subtherapeutic) - Completed**

- 20 μg x 1 x1 Laser
- 40 μg x 1 x1 Laser
- 80 μg x 1 x1 Laser

3 subjects per cohort

**Multiple Dose Cohorts - Completed**

- 40 μg x 2 x1 Laser
- 40 μg x 3 x1 Laser
- 80 μg x 1 x2 Lasers
- 80 μg x 1 x1 Laser
- 80 μg x 3 x2 Lasers
- 80 μg x 1 x1 Laser
- 80 μg x 3 x1 Laser

3 subjects per cohort

**Expansion Cohort – Currently enrolling**

- Dose Expansion
- Started mid Sep

12 subjects in Expansion Cohort
Maximum tolerated and feasible dose - 80μ x 3 x 2 Lasers
Durability of tumor response with vision preservation at 12 months

Data represented in graph is an average of three readers.

Patient with documented tumor growth and orange pigment
Location: 0 mm to optic disk

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AU-011 is an investigational drug and not approved for choroidal melanoma.
A Phase 1b/2 Open-label, Ascending Single and Repeat Dose Clinical Trial Designed To Evaluate the Safety and Efficacy of Light-activated AU-011 for the Treatment of Subjects with Small & Medium Primary Choroidal Melanoma

- Brian Marr, Abdhish Bhavsar, Antonio Capone, Hakan Demirci, Peter Hovland, Ivana Kim, Tara McCannel, Amy Schefler, & Carol Shields

Brian Marr, MD presenting – Monday, October 29th @ 3:57pm
Experienced Board & Strong Investor Syndicate

Board of Directors

- Henri Termeer (in memoriam)
- Casper Breum
- Mark Chin
- Joel Jean-Mairet, Ph.D.
- Arthur Pappas
- Dale Pfost, Ph.D.
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Investor Syndicate

Series C - $30M (2017-2018)
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- Advent Life Sciences
- YSIOS CAPITAL

Series B - $29M (2015-2016)
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- LI-COR
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