

## Corporate Presentation March 2024

## Envisioning a new way to treat cancer



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## Aura Biosciences – Developing a Novel Class of Drugs in Oncology

VIRUS LIKE DRUG CONJUGATES (VDCs) FOR THE TREATMENT OF SOLID TUMORS

- Choroidal Melanoma Global Ph 3 CoMpass Trial:
  - FPI was Q4 2023
  - Most US sites activated; Trial actively enrolling
  - Special Protocol Assessment (SPA) Agreement with FDA
  - Ph 3 assumptions supported by Ph 2 data
- Choroidal Metastasis Ph 2 trial planned to initiate in mid-2024
- Second ocular indication potentially doubles market opportunity
- Clinical complete response in first patient with single dose
- Data supports dual mechanism
- Updated protocol includes both NMIBC and MIBC
- Current cash runway expected to fund operations into 2H 2026

**Ocular Oncology Franchise** 

**Urologic Oncology Franchise** 

**Strong Cash Position** 



## Pipeline Targeting Life-Threatening Cancers with High Unmet Needs

| Program   | Preclinical | Phase 1 | Phase 2 | Phase 3 | Program Status  |
|---|-------------|---------|---------|---------|---|
| OCULAR ONCOLOGY   |             |         |         |         |   |
| Primary Choroidal Melanoma<br>(Suprachoroidal administration)   |             |         |         |         | <b>2024</b> – Ph 3 enrollment ongoing<br><b>YE 2024</b> – Ph 2 12-month SC data |
| <b>Choroidal Metastasis</b><br>(Multiple primary cancers with metastasis in the eye<br>e.g., Breast and Lung) |             |         |         |         | <b>YE 2024</b> – Ph 2 data  |
| Cancers of the Ocular Surface   |             |         |         |         |   |
| OTHER SOLID TUMORS  |             |         |         |         |   |
| Bladder Cancer<br>(NMIBC and MIBC)  |             |         |         |         | <b>Mid-2024</b> – Ph 1 data   |
| <b>Other HSPG* Expressing Tumors</b><br>(e.g., Cutaneous melanoma, HNSCC)                                     |             |         |         |         |   |

**Global Commercial Rights for All Product Candidate Indications** 



## Targeted Oncology Platform: Virus-Like Drug Conjugates (VDCs)

Virus-Like Particle Conjugated to a Cytotoxic Payload

Selective Binding to **Tumor Associated HSPGs\*** 

#### Potential Treatment of Multiple Solid Tumors







Virus-Like Particle (VLP)

Cytotoxic Drug





#### Potential Key Differentiation: Potency, Multivalent Binding and Selectivity

Kines et al; International Journal of Cancer, 138;901–911, February 2016; Kines et al; Molecular Cancer Therapeutics, 17(2) February 2018; Kines et al; Cancer Immunology Research, May 2021 \*VDCs bind to a subset of modified tumor associated glycosaminoglycans (GAGs) that are part of the heparan sulphate chain of HSPGs. Schiller et al. Viruses 2022, 14(8), 1656

## Bel-sar is a VDC with a Novel Dual Mechanism of Action



#### Potential Key Differentiation: Agnostic to Genetic Mutations, Less Susceptible to Resistance Mechanisms, Long Term Anti-tumor Immunity

Kines et al; Cancer Immunology Research, May 2021

VDCs bind to a subset of modified tumor associated glycosaminoglycans (GAG) that are part of the heparan sulphate chain of HSPGs. Schiller et al. Viruses 2022, 14(8), 1656 Bel-sar – Belzupacap Sarotalocan

## Ocular Oncology Franchise





### Target Indications:

- Early-Stage Choroidal Melanoma
- Choroidal Metastasis
- Other Ocular Cancers

## Primary Choroidal Melanoma—High Unmet Medical Need



#### Choroidal Melanoma is a Rare and Life-Threatening Primary Ocular Cancer with No Drugs Approved

- 1. Heiting, G. Iris/uvea of the eye. Accessed Oct. 3, 2023. https://www.allaboutvision.com/en-gb/resources/uvea-iris-choroid/
- 2. Kaliki S, Shields CL. Uveal melanoma: relatively rare but deadly cancer. Eye (Lond). 2017;31(2):241-257. doi:10.1038/eye.2016.275
- 3. Clearview & Putnam & Assoc. Market Research

## Radiotherapy is the Standard of Care for Early-Stage Disease

Plaque Brachytherapy for Choroidal Melanoma Requires Invasive Surgery with Irreversible Complications and Does Not Prevent Metastasis



(A) Schematic drawing showing a Collaborative Ocular Melanoma Study (COMS) style plaque sutured to the sclera overlying the location of the uveal melanoma<sup>1</sup>

(B) Intraoperative photograph showing COMS plaque in place. The plaque stays in place for 3 to 7 days<sup>1</sup>



Surgical treatment of large choroidal melanoma with ruthenium 106 plaque brachytherapy<sup>2</sup>

#### Maculopathy, Cataract, Glaucoma, Vitreous Detachment and Vitreous Hemorrhage are Common Vision Threatening Complications of Brachytherapy<sup>3</sup>

- 1. Up To Date. Plaque brachytherapy for uveal melanoma. Accessed September 20, 2023. https://ykhoa.org/d/image.htm?imageKey=ONC/116591
- 2. Kim M, Lee SM, Lee. Surgical treatment of a large choroidal melanoma. American Academy of Optometry 2022 Video Program. March 1, 2023. Accessed September 20, 2023.
- https://www.aao.org/education/annual-meeting-video/surgical-treatment-of-large-choroidal-melanoma



3. Peddada KV, Sangani R, Menon H, Verma V. Complications and adverse events of plaque brachytherapy for ocular melanoma. J Contemp Brachytherapy. 2019;11(4):392-397. doi:10.5114/jcb.2019.8740

## Up to 87% of Patients Will be Blinded when Treated with Radiotherapy

## Proportion of Patients Legally Blind (BCVA ≤20/200) after Brachytherapy<sup>1,2</sup>



Contrast Sensitivity Diminishes Significantly within the First Year after Brachytherapy and Continues to Deteriorate Over Time<sup>2</sup>



Normal Vision

Vision with Reduced Contrast Sensitivity

#### Visual Acuity, Color Vision and Contrast Sensitivity Decrease Significantly within the First Year after Treatment and Continue to Decrease Over Time

- 1. Jarczak J, Karska-Basta I, Romanowska-Dixon B. Deterioration of visual acuity after brachytherapy and proton therapy of uveal melanoma, and methods of counteracting this complication based on recent publications. *Medicina* (Kaunas). 2023;59(6):1131.
- 2. Tsui I, Beardsley RM, McCannel TA, Oliver SC, et al. Visual acuity, contrast sensitivity and color vision three years after iodine-125 brachytherapy for choroidal and ciliary body melanoma. *Open Ophthalmol J*. 2015;9:131-5.

# Benefit/Risk of Radiotherapy Drives "Watch and Wait" in Patients with Early-Stage Disease



1. Clearview & Putnam & Assoc. Market Research

2. Kaliki S, Shields CL. Uveal melanoma: relatively rare but deadly cancer. Eye (Lond). 2017;31(2):241-257. doi:10.1038/eye.2016.275



## Bel-sar has the Potential to be the First Approved Therapy in Primary Choroidal Melanoma



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## Ocular Oncology Franchise Represents a Multi-Billion Dollar Addressable Market Opportunity

#### ~66,000 patients/year 11,000 patients/year Ocular Oncology Franchise total addressable market (US/EU) Choroidal Melanoma patients diagnosed each year (US/EU) ~35,000 patients/year<sup>3</sup> 11,000 patients/year<sup>1</sup> ~80% **Current radiotherapy** Cancers of the Ocular Surface Choroidal Melanoma treatment of patients are diagnosed Leaves ~87% of patients with Multibillion \$ at the early stage major irreversible vision loss (indeterminate lesions addressable (ILs) and small tumors) market opportunity **Field Based Team Choroidal Metastasis Ocular Oncologists in** Retinoblastoma Intend to add small **US/EU** — focused call 20,000 patients/year<sup>1</sup> **500** patients/year<sup>2</sup> sales force point to launch globally

1. ClearView & Putnam & Assoc. Epidemiology Analysis Choroidal Melanoma and Choroidal Metastasis

2. American Cancer Society- Retinoblastoma statistics

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3. Includes Conjunctival Melanoma, Primary Acquired Melanosis, Squamous Cell Carcinoma and Ocular Surface Squamous Neoplasia

(https://pubmed.ncbi.nlm.nih.gov/12788119/; https://pubmed.ncbi.nlm.nih.gov/19628487/; https://pubmed.ncbi.nlm.nih.gov/8676629/;

https://pubmed.ncbi.nlm.nih.gov/29511061/; https://pubmed.ncbi.nlm.nih.gov/9037556/)

## **Potential Future Patient Treatment Journey**



Bel-Sar has the Potential to be an Effective, Vision Preserving Therapy for the Treatment of Indeterminate Lesions and Small Choroidal Melanoma

1. Clearview & Putnam & Assoc. Market Research

2. Kaliki S, Shields CL. Uveal melanoma: relatively rare but deadly cancer. Eye (Lond). 2017;31(2):241-257. doi:10.1038/eye.2016.275

# Bel-sar has Demonstrated a Favorable Profile for the Treatment of Early-Stage Disease

| Adverse Event or Adverse Reactions | KIMMTRAK <sup>1</sup> | Darovasertib + Crizotinib<br>Combination <sup>2</sup> | Bel-Sar    |
|------------------------------------|-----------------------|---|------------|
|                                    | Any Grade             | Any Grade   | Any Grade* |
| Cytokine release syndrome          | 89%                   | Not Disclosed   | 0%         |
| Rash                               | 83%                   | Not Disclosed   | 0%         |
| Pyrexia                            | 76%                   | Not Disclosed   | 0%         |
| Pruritus                           | 69%                   | Not Disclosed   | 0%         |
| Fatigue                            | 64%                   | 40%   | 0%         |
| Nausea                             | 49%                   | 79%   | 0%         |
| Vomiting                           | Not Disclosed         | 52%   | 0%         |
| Chills                             | 48%                   | Not Disclosed   | 0%         |
| Hypo-/hyperpigmentation            | 47%                   | Not Disclosed   | 0%         |
| Abdominal pain                     | 45%                   | Not Disclosed   | 0%         |
| Edema                              | 45%                   | 57%   | 0%         |
| dermatitis acneiform               | Not Disclosed         | 44%   | 0%         |
| Hypotension                        | Not Disclosed         | 34%   | 0%         |
| Hypoalbuminemia                    | Not Disclosed         | 32%   | 0%         |
| Dizziness                          | Not Disclosed         | 28%   | 0%         |

1. Immunocore Corporate Presentation. 2023 August. Slide 12. https://ir.immunocore.com/static-files/415c5cbb-caae-4ffa-9beb-cb40cfcfc132

2. IDEAYA Clinical Update Presentation. 2023 April 24. Slide 10.

Note: Certain data in this presentation are based on a cross-trial comparisons and are not based on any head-to-head clinical trials. Cross-trial comparisons are inherently limited and may suggest misleading similarities or differences. Results of head-to-head comparisons may differ significantly from those set forth herein.

\*Safety outcomes for ongoing Ph2 study with bel-sar presented on slide 22

## Choroidal Melanoma Ph 2 Data





# Ph 2 Trial – Dose Escalation and Expansion with Suprachoroidal Administration

Patient Population Representative of Early-Stage Disease: Indeterminate Lesions and Small Choroidal Melanoma

| Endpoint                    | Endpoint Definitions   | Trial Design – Enrollment Complete (n=22)  |
|-----------------------------|--|--|
| Tumor Progression           | Growth in Tumor Height<br>≥0.5mm or ≥1.5 mm in Largest<br>Basal Diameter (LBD) | $1 \operatorname{dose-20 \ \mu g}_{x \ 1 \ Laser} \xrightarrow{1 \ \operatorname{dose-40 \ \mu g}} 1 \operatorname{dose-40 \ \mu g}_{x \ 2 \ Lasers} \xrightarrow{2 \ \operatorname{doses-40 \ \mu g}} \underbrace{2 \ \operatorname{doses-40 \ \mu g}}_{QWx2} \xrightarrow{6-9 \ \operatorname{doses-40 \ \mu g}} \xrightarrow{9 \ \operatorname{doses-80 \ \mu g}} \underbrace{2 \ \operatorname{Lasers}}_{QWx3} \xrightarrow{9 \ \operatorname{doses-80 \ \mu g}}_{QWx3}$ |
| Visual Acuity Loss          | Decrease from Baseline:<br>≥15 letters   | Cohort 1 (n=1) Cohort 2 (n=3*) Cohort 3 (n=2) Cohort 4 (n=3) Cohort 5 Cohort 6<br>2 Cycles (n=1)3 Cycles (n=2) (n=up to 10)  |
| Tumor Thickness Growth Rate | Change in Rate of Growth of<br>Tumor Thickness                                 | Subtherapeutic Regimens       Therapeutic Regimen         N=10       N=11**         1- 2 Doses (n=9); 2 cycles-6 doses (n=1)       3 Cycles (9 doses)  |
|                             |  | One Cycle = Doses on days 1, 8, and 15   |

Goal: To Determine Safety, Optimal Dose and Therapeutic Regimen with Suprachoroidal Administration

\*Cohort 2: 2 subjects were planned; third subject was additionally enrolled due to dose error in 1 subject

\*\*12 patients enrolled, 1 subject who discontinued after 1 cycle due to unrelated SAEs is not included in data analysis (n=11). Data that follows will be based on a cohort of 11 ClinicalTrials.gov Identifier: NCT04417530 ; AU-011-202

## High Local Complete Response Rate at 12 Months Follow Up\*

#### Dose Response: Subtherapeutic vs Therapeutic Regimen



| Dose/Regimen                       | Total Patients<br>(n) | Tumor Control<br>Rate |
|------------------------------------|-----------------------|-----------------------|
| Subtherapeutic Regimens            |                       |                       |
| Single dose up to 2 cycles         | 10                    | 20% (2/10)            |
| Therapeutic Regimen                |                       |                       |
| 3 Cycles (n=11)                    | 11                    | 73% (8/11)            |
| 3 Cycles and Ph 3 eligible (n=10)* | 10                    | 80% (8/10)            |

>90% Completed 12 Months

\* One subject with circumpapillary tumor that did not meet Ph 3 criteria is not included

Tumor Progression: change from baseline in thickness  $\geq 0.5$  mm; or in LBD  $\geq 1.5$  mm confirmed by at least one repeat assessment August 3, 2023, data on file Aura Biosciences

#### High Local Complete Response Rate with Therapeutic Regimen in Ph 3 Eligible Patients with Active Growth

\*A local complete response, or CR, in early-stage choroidal melanoma is described as tumor control and complete arrest of tumor growth by ocular oncologists.

## Durable Local Complete Response Rates Observed in Ph 3 Population Treated with Therapeutic Regimen\*

### Subtherapeutic Regimens (n=10)

#### Active Growth and 3 Cycle Regimens (n=10)



August 3, 2023, data on file Aura Biosciences

#### Ph 2 Interim Data Demonstrated Tumor Control Rate of 80%, with 90% of Patients at 12 Months of Follow Up

\*A local complete response, or CR, in early-stage choroidal melanoma is described as tumor control and complete arrest of tumor growth by ocular oncologists.

## Negative Growth Rate Post-Treatment in Patients with Local Complete Responses\*

#### Successful Treatment with 3 Cycle Regimen in Ph 3 Eligible Tumors with Active Growth Change in Tumor Growth (mm/yr) (n=8)



August 3, 2023, data on file Aura Biosciences

Tumor thickness growth rates/ slopes estimated using Mixed Models for Repeat Measures (random intercept and slope model for Historical and Study periods)

#### Interim Data Showed Negative Growth Rate Among Responders in Planned Ph 3 Population (P < 0.0001)

## 90% Visual Acuity Preservation Despite 80% of These Patients Being at High Risk for Vision Loss



90% Visual Acuity Preservation Data Supports Potential to be Front Line Therapy for Early-Stage Disease

# Ph 2 Safety Data Supports Potential to be First Line Treatment in Early-Stage Disease

| Ongoing Ph 2 Safety Outcomes with SC Administration                               |         |          |           |       |
|---|---------|----------|-----------|-------|
| All Treated Subjects (n=22)<br>Drug/Laser Related Adverse Events<br>>5% Subjects* | Grade I | Grade II | Grade III | Total |
| Anterior Chamber<br>Inflammation  | 18%     | 0        | 0         | 18%   |
| Anterior Chamber Cell   | 9%      | 0        | 0         | 9%    |
| Eye Pain  | 9%      | 0        | 0         | 9%    |

Table presents percentage of subjects with AEs related to bel-sar or laser by severity and overall; subjects with more than 1 AE are counted in the highest severity group

\*Treatment-emergent AEs related to bel-sar or laser in 1 patient each or <5% (anisocoria, conjunctival edema, cystoid macular edema, pupillary reflex impaired, retinal pigment epitheliopathy, salivary gland enlargement)

August 3, 2023, data on file Aura Biosciences

| Adverse Event                                 | Radiotherapy* | Bel-Sar⁺ |
|---|---------------|----------|
| Surgeries secondary to AEs⁺ (e.g., Cataracts) | 40%+          | 0%       |
| Radiation Retinopathy                         | 40%+          | 0%       |
| Neovascular Glaucoma                          | 10%           | 0%       |
| Dry Eye Syndrome                              | 20%           | 0%       |
| Strabismus                                    | 2%+           | 0%       |
| Retinal Detachment                            | 1-2%          | 0%       |
| Vision Loss (≥15 letters)                     | ~70%          | ~5%      |
| Serious Adverse Event                         | Radiotherapy* | Bel-Sar⁺ |
| Scleral Necrosis                              | 0-5%          | 0%       |
| Enucleation/Eye Loss                          | 10-15%        | 0%       |
| Severe Vision Loss (≥30 letters) in HRVL**    | ~90%          | 0%++     |

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+Related to bel-sar or laser

\*\*73% (16/22) of patients in Ph2 SC trial were at high risk for vision loss

#### No Posterior Inflammation, No SAEs and No Grade 3 Related Adverse Events

\*J. Contemp Brachytherapy. J. 2019 Aug; 11(4): 392–397.; Arch Ophthalmol. 2000;118(9):1219-1228; Curr. Opin. Ophthalmol. 2019 May; 30(3): 206-214; Eye 2017 Feb; 31(2): 241-257 \*\* High-Risk Vision Loss (HRVL) are those subjects with tumors <3mm to fovea or optic nerve

Bel-Sar – Belzupacap Sarotalocan; AEs – Adverse Events; SAEs – Serious Adverse Events

## Randomized Controlled Global Ph 3 Trial





## SPA Agreement with FDA Supports Global Ph 3 Trial Design Fast Track and Orphan Designations





Kaplan-Meier Analysis Simulation of Key Primary & Secondary Endpoint with Ph 2 Data



Note: Subjects either had an event or were censored at the last visit. Some subjects had Week 52 visit after 365 days.

Time to Composite Endpoint is defined as time to tumor progression or vision acuity failure, whichever occurs earlier.

Tumor progression is defined as a change from baseline in thickness ≥0.5mm; or in LBD ≥1.5mm confirmed by at least one repeat assessment.

Log-rank test p-value based on unsimulated original KM curves

August 3, 2023 data on file Aura Biosciences

Study duration 12 months. Some patients presented delayed for their final 12-month visit. Any events at the final visit are assigned to the actual time of that visit.

#### Ph 2 Interim Data Supports Assumptions for the Potential Success of Ph 3 with High Statistical Significance

## Choroidal Metastasis





## Choroidal Metastasis is a High Unmet Medical Need



#### Choroidal Metastasis Cause Decreased Vision and Decreased Quality of Life in Patients Fighting Metastatic Cancer

Mathis et al. New concepts in choroidal metastasis, Progress in retinal and eye research (2019), Cohen, Ocular metastasis, Eye (2014), Shields et al. Survey of 520 eyes with uveal metastases. Ophthalmology (1997), Namad et al. Bilateral choroidal metastasis from non-small lung cancer, Case reports in oncological medicine (2014).



## Choroidal Metastasis – Ph 2 Trial Design



Highlights: Primary Endpoint at one-month post-treatment; possibility to see tumor shrinkage; FDA oncology division

## Urologic Oncology

Bel-sar INN: belzupacap sarotalocan



Target Indications: Bladder Cancer



## Bladder Cancer is a High Unmet Medical Need



- Campbell-Walsh-wein Urology, 2021, 12th edition ; Chapter 137, page 3112 2.

## Bel-Sar has the Potential to be Front Line in Conjunction with TURBT



## Bel-Sar has a Unique MoA Designed for the Local Treatment

Local Administration and Light Activation with Standard Cystoscope

**Treatment Aligned with Current Urologic Oncology Practice** 



| Lasers are commonly used<br>by urologists                         | Bladder injections are<br>common and simple to<br>perform (e.g., Botox)              |
|---|--|
| Local delivery in the bladder<br>increases tumor drug<br>exposure | Precedent for<br>immune-mediated tumor<br>clearance (BCG & checkpoint<br>inhibitors) |

Bel-sar's Local Administration is Aligned with Clinical Practice and has a Unique MoA that may be Complementary to Other Drugs

## Ph 1 Trial Designed to Evaluate Safety, Feasibility and MoA



Ph 1 Data is Anticipated to Support the Future Development of Bel-sar for the Treatment of Both NMIBC and MIBC



## Clinical Complete Response with Immune Activation after Single Dose Confirmed by Histopathology



### Day 1

Diagnostic biopsy shows noninvasive, low grade urothelial carcinoma

Injection of Bel-sar (100ug) performed within tumor and below tumor

(Aura present w/ Urologist)

## Day 2 🗸

Urologist performs Light activation with 689nm infrared light (50J/cm<sup>2</sup>) (~5 min duration) (Aura present w/ Urologist)

### Day 9

Urologist performs TURBT in area where tumor used to be present. Biopsy shows denuded urothelial mucosa,

no cancer cells;

focal ulcer and chronic inflammation (eosinophils/lymphocytes)

## Pre-Treatment Biopsy (Day 1) shows Papillary Urothelial Carcinoma



Pre-injection bladder biopsy demonstrating low-grade papillary urothelial carcinoma; non-invasive.

Clinical Complete Response Confirmed by Histopathology after Single Dose of Bel-sar Disappearance of all cancer cells after treatment and immune activation





Post-treatment TURBT demonstrating necrosis, inflammatory infiltrate, and no residual carcinoma. Circled region shows area of necrosis; arrow indicates edge of inflammatory infiltrate.

**Evidence of Complete Response by Absence of Tumor Cells after Single Dose Treatment in First Patient** 



## Durable CRs with Single Administration of Bel-sar in Bladder Cancer Model

Treatment of Tumor Caused Anti-Tumor Immune Response and Prevented Tumor Growth After Re-Challenge



Syngeneic Mouse Tumor Bladder Model (MB49 Model in C57BL/6 Mice) (N=8 -10/group)

Kines et al. Can Immunol Res 9(6):693-706, 2021

Data Demonstrated Robust Nonclinical Activity Supporting Development of Bel-sar as Single Agent and in Combination with Checkpoint Inhibitors

## Strategy & Key Milestones





## Aura Biosciences – Developing a Novel Class of Drugs in Oncology

VIRUS LIKE DRUG CONJUGATES (VDCs) FOR THE TREATMENT OF SOLID TUMORS

| Ocular Oncology Franchise   | <ul> <li>Choroidal Melanoma – Global Ph 3 CoMpass Trial:         <ul> <li>FPI was Q4 2023</li> <li>Most US sites activated; Trial actively enrolling</li> <li>Special Protocol Assessment (SPA) Agreement with FDA</li> <li>Ph 3 assumptions supported by Ph 2 data</li> </ul> </li> <li>Choroidal Metastasis – Ph 2 trial planned to initiate in mid-2024</li> <li>Second ocular indication potentially doubles market opportunity</li> </ul> |
|-----------------------------|--|
| Urologic Oncology Franchise | <ul> <li>Clinical complete response in first patient with single dose</li> <li>Data supports dual mechanism</li> <li>Updated protocol includes both NMIBC and MIBC</li> </ul>  |
| Strong Cash Position        | Current cash runway expected to fund operations into 2H 2026   |

