UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): February 16, 2023

Aura Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-40971**	**32-0271970**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

80 Guest Street **Boston, MA** **(Address of principal executive offices)**	**02135** **(Zip Code)**

Registrant's telephone number, including area code (617) 500-8864

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trade Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.00001 par value per share	AURA	The Nasdaq Global Market

Item 7.01 Regulation FD Disclosure.

On February 16, 2023, Aura Biosciences, Inc. (the "Company") issued a press release titled "Aura Biosciences Announces Positive Interim Phase 2 Safety and Efficacy Data of Belzupacap Sarotalocan (Bel-sar) for the First-Line Treatment of Patients with Early-Stage Choroidal Melanoma with Suprachoroidal Administration at the Macula Society 46th Annual Meeting." A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On February 16, 2023, the Company updated its corporate presentation for use in meetings with investors, analysts and others. A copy of the corporate presentation is filed as Exhibit 99.2 for purposes of Section 18 of the Exchange Act.

Forward Looking Statements

Statements contained under this Item 8.01 regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements about the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs; our ability to successfully manufacture our drug substances and product candidates for preclinical use, for clinical trials and on a larger scale for commercial use, if approved; the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates; our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates; our ability to obtain and maintain regulatory approval of our product candidates; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; our financial performance; the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and clinical trials and any future studies or trials; our ability to commercialize our products, if approved; and the implementation of our business model, and strategic plans for our business and product candidates.

Any forward-looking statements are neither promises nor guarantees, and investors should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond the Company's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including, without limitation, an improved quality of life of patients after treatment with belzupacap sarotalocan; a potential paradigm shift in the approach to the treatment of choroidal melanoma; the urgent need for a vision preserving targeted therapy; the potential of belzupacap sarotalocan compared to the existing standard of care for patients with choroidal melanoma; uncertainties inherent in clinical trials and in the availability and timing of data from ongoing clinical trials; the expected timing for submissions for regulatory approval or review by governmental authorities; the risk that the results of the Company's clinical trials may not be predictive of future results in connection with future clinical trials; the risk that interim data from ongoing clinical trials may not be predictive of final data from completed clinical trials; whether the Company will receive regulatory approvals to conduct trials or to market products; whether the Company's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; risks, assumptions and uncertainties regarding the impact of the

continuing COVID-19 pandemic on the Company's business, operations, strategy, goals and anticipated timelines; the Company's ongoing and planned pre-clinical activities; and the Company's ability to initiate, enroll, conduct or complete ongoing and planned clinical trials. These risks, uncertainties, and other factors include those risks and uncertainties described under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC") and in subsequent filings made by the Company with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on the Company's current expectations and speak only as of the date hereof and no representations or warranties (express or implied) are made about the accuracy of any such forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated February 16, 2023, entitled "Aura Biosciences Announces Positive Interim Phase 2 Safety and Efficacy Data of Belzupacap Sarotalocan (Bel-sar) for the First-Line Treatment of Patients with Early-Stage Choroidal Melanoma with Suprachoroidal Administration at the Macula Society 46th Annual Meeting"
99.2	Corporate presentation of the Company
104	Cover Page Interactive Data (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 16, 2023

AURA BIOSCIENCES, INC.

By: /s/ Julie Feder
Julie Feder
Chief Financial Officer

Aura Biosciences Announces Positive Interim Phase 2 Safety and Efficacy Data of Belzupacap Sarotalocan (Bel-sar) for the First-Line Treatment of Patients with Early-Stage Choroidal Melanoma with Suprachoroidal Administration at the Macula Society 46th Annual Meeting

Boston, MA – Feb. 16, 2023 – Aura Biosciences, Inc. ("Aura") (Nasdaq: AURA), a clinical-stage biotechnology company developing a novel class of virus-like drug conjugate (VDC) therapies for multiple oncology indications, today announced the presentation of positive interim Phase 2 safety and efficacy data of bel-sar with 9-10 months of follow up evaluating two key clinical endpoints: tumor control and visual acuity preservation using the suprachoroidal (SC) route of administration for the first-line treatment of patients with early-stage choroidal melanoma (indeterminate lesions and small choroidal melanoma (IL/CM)). The results were presented at the Macula Society 46th Annual Meeting held February 15-18, 2023, in Miami, FL.

"The data presented today with an average of nine months of follow up for patients treated with three cycles of therapy, show an excellent response to the therapy with 89-100% tumor control. In addition, the safety profile to date has been favorable with only one patient losing visual acuity and no treatment-related SAEs or significant AEs, which is encouraging given that the majority of these patients had tumors close to the fovea or optic disk and would have likely experienced severe and irreversible vision loss with the current standard of care with radiotherapy," said Dr. Ivana Kim, Director of the Ocular Melanoma Center, Massachusetts Eye and Ear. "These latest results strongly support the potential of bel-sar to be used as a first line treatment option for patients with early-stage choroidal melanoma."

"We are excited with the interim efficacy data of the Phase 2 study which strongly supports the assumptions for the success of the global Phase 3 trial," said Dr. Cadmus Rich, Chief Medical Officer of Aura Biosciences. "Collectively, we believe these interim data provide strong confidence to support the launch of a global Phase 3 trial which is on track to begin enrollment this year."

The presentation can be accessed on the Company's website: link

Updated Safety and Efficacy Data from the Ongoing Phase 2 Trial with SC Administration

This Phase 2 trial (NCT04417530) is assessing the safety and preliminary efficacy of single- and multiple ascending-doses of bel-sar up to three cycles of treatment via SC administration for the first-line treatment of early-stage choroidal melanoma. A total of 20 adult patients have been enrolled in the trial including the single dose Cohorts 1-3 (n=6) and multiple dose escalation Cohorts 4-6 (n=14). Cohorts 5 and 6 received up to three cycles of therapy, which was considered the therapeutic regimen for evaluation. One patient in Cohort 5 (n=3) received two cycles of therapy and two patients in Cohort 5 received three cycles of therapy (40 µg/dose). All patients from Cohort 6 (n=8) were assigned to receive three cycles of therapy at the highest dose (80 µg/dose). One patient from Cohort 6, who discontinued after one cycle due to unrelated serious adverse events (SAEs), is not included. All patients in Cohorts 5 and 6 had active growth at study entry, as an enrichment strategy to evaluate preliminary efficacy. This group of patients with active growth treated at the therapeutic regimen of three cycles was evaluated for tumor growth rate, tumor control, and visual acuity preservation as the defined clinical endpoints to evaluate preliminary efficacy. The results, with an average of nine months of follow up in patients who received three cycles of therapy in Cohorts 5 and 6, and who match the criteria for the planned global Phase 3 trial, showed a

statistically significant reduction in the tumor growth rate (-0.289 mm/yr, p = <0.0001) compared to each patient's documented growth rate at study entry, and a 100% (8/8) tumor control rate. In addition, the visual acuity preservation rate was 88% (7/8) in these cohorts, with the majority of patients being at high-risk for vision loss with tumors close to fovea or optic disk. The overall tolerability profile of bel-sar was generally favorable, with no dose-limiting toxicities, treatment-related SAEs or significant AEs reported as of January 10, 2023. There was no posterior inflammation and only mild anterior inflammation (Grade 1) in 20% of the patients. Treatment-related AEs were predominantly mild and resolved without sequalae. We believe these interim results indicate that bel-sar may offer a targeted, vision preserving therapy for the first-line treatment of primary CM, where 80% of patients are diagnosed early and have no approved therapies to date.

About Aura Biosciences

Aura Biosciences, Inc. is a clinical-stage biotechnology company developing virus-like drug conjugates (VDCs), a novel class of therapies, for the treatment of multiple oncology indications. Aura's lead VDC candidate, belzupacap sarotalocan (bel-sar; AU-011), consists of a virus-like particle conjugated with an anti-cancer agent. Bel-sar is designed to selectively target and destroy cancer cells and activate the immune system with the potential to create long-lasting anti-tumor immunity. Bel-sar is currently in development for ocular cancers, and Aura has initiated activities for the global Phase 3 trial evaluating first-line treatment of early-stage choroidal melanoma, a vision- and life-threatening form of eye cancer where standard of care with radiotherapy leaves patients with severe comorbidities, including major vision loss. Aura plans to pursue development of bel-sar across its ocular oncology franchise including for the treatment of patients with choroidal metastasis. In addition, leveraging Aura's technology platform, Aura is developing bel-sar more broadly across multiple cancers, including in patients with non-muscle invasive bladder cancer (NMIBC). Aura is headquartered in Boston, MA.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other federal securities laws. Any statements that are not statements of historical fact may be deemed to be forward looking statements. Words such as "may," "will," "could", "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "seeks," "endeavor," "potential," "continue" or the negative of such words or other similar expressions that can be used to identify forward-looking statements. These forward looking statements include express or implied statements regarding Aura's future expectations, plans and prospects, including, without limitation, statements regarding the therapeutic potential of bel-sar for the treatment of cancers including choroidal melanoma, non-muscle invasive bladder cancer and choroidal metastases; any express or implied statements regarding the Company's expectations for the Phase 2 and Phase 3 clinical trials of bel-sar for early-stage choroidal melanoma; and Aura's expectations regarding the estimated patient populations and related market opportunities for bel-sar.

The forward-looking statements in this press release are neither promises nor guarantees, and investors should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Aura's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including, without limitation, an improved quality of life of patients after treatment with bel-sar; a potential paradigm shift in the approach to the treatment of choroidal melanoma; the urgent need for a vision preserving targeted therapy; the potential of bel-sar compared to the existing standard of care for patients with choroidal melanoma; uncertainties inherent in clinical trials and in the availability and timing of data from ongoing clinical trials; the expected timing for submissions for regulatory approval or review

by governmental authorities; the risk that the results of Aura's clinical trials may not be predictive of future results in connection with future clinical trials; the risk that interim data from ongoing clinical trials may not be predictive of final data from completed clinical trials; whether Aura will receive regulatory approvals to conduct trials or to market products; whether Aura's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; risks, assumptions and uncertainties regarding the impact of the continuing COVID-19 pandemic on Aura's business, operations, strategy, goals and anticipated timelines; Aura's ongoing and planned pre-clinical activities; and Aura's ability to initiate, enroll, conduct or complete ongoing and planned clinical trials. These risks, uncertainties, and other factors include those risks and uncertainties described under the heading "Risk Factors" in Aura's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Aura with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Aura disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Aura's current expectations and speak only as of the date hereof and no representations or warranties (express or implied) are made about the accuracy of any such forward-looking statements.

Investor and Media Contact:

Alex Dasalla
Head of Investor Relations and Corporate Communications
adasalla@aurabiosciences.com

Argot Partners
Matthew DeYoung
aura@argotpartners.com

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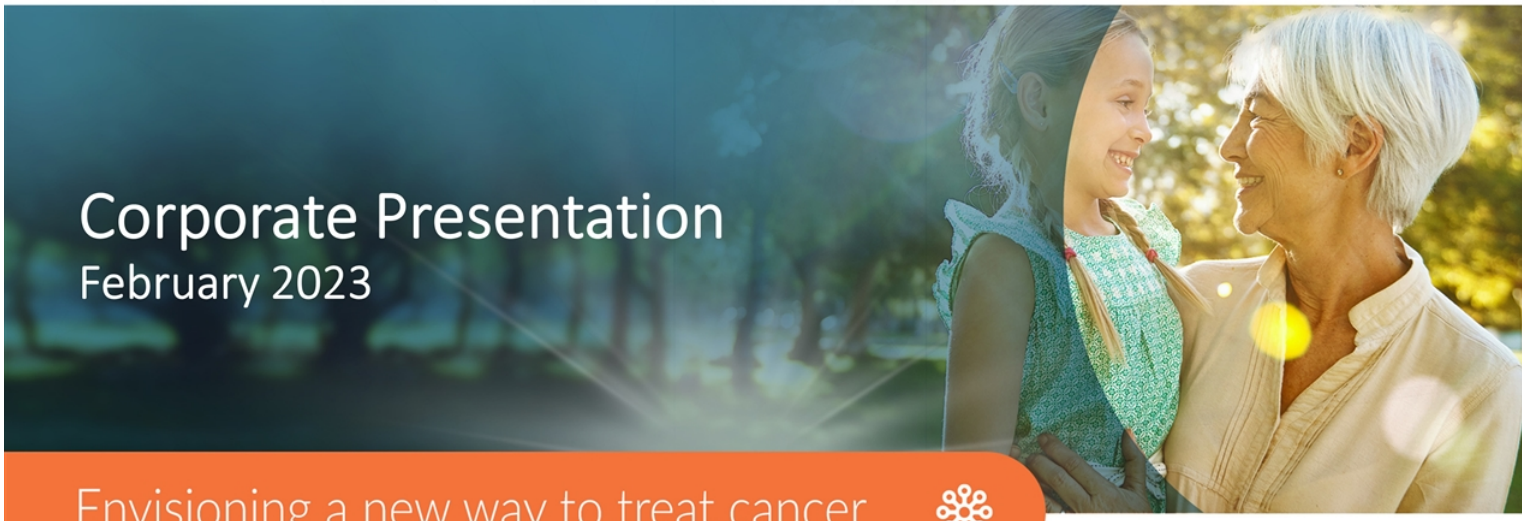

Corporate Presentation

February 2023

Envisioning a new way to treat cancer

Legal Disclosure

This presentation contains forward-looking statements, all of which are qualified in their entirety by this cautionary statement. Many of the forward-looking statements contained herein can be identified by the use of forward-looking words such as "may", "anticipate", "believe", "could', "expect", "should", "plan", "intend", "estimate", "will", "potential" and "ongoing", among others, although not all forward-looking statements contain these identifying words. These forward-looking statements include statements about the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs; our ability to successfully manufacture our drug substances and product candidates for preclinical use, for clinical trials and on a larger scale for commercial use, if approved; the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and product candidates; our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates; our ability to obtain and maintain regulatory approval of our product candidates; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; our financial performance; the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and clinical trials and any future studies or trials; our ability to commercialize our products, if approved; and the implementation of our business model, and strategic plans for our business and product candidates.

Except as otherwise noted, these forward-looking statements speak only as of the date of this presentation, and we undertake no obligation to update or revise any of such statements to reflect events or circumstances occurring after this presentation. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent annual report on Form 10-K filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in our other subsequent filings with the Securities and Exchange Commission. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. We caution you not to place undue reliance on the forward-looking statements contained in this presentation.

This presentation discusses product candidates that are under preclinical or clinical evaluation and that have not yet been approved for marketing by the U.S. Food and Drug Administration or any other regulatory authority. Until finalized in a clinical study report, clinical trial data presented herein remain subject to adjustment as a result of clinical site audits and other review processes. No representation is made as to the safety or effectiveness of these product candidates for the use for which such product candidates are being studied.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

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Aura Biosciences Highlights

Novel Platform to Treat Multiple Solid Tumors

- Developing virus-like drug conjugates (VDCs) that bind to tumor specific HSPGs* to deliver a therapeutic payload
- Targeting multiple solid tumor indications including ocular and bladder cancers

Ocular Oncology Franchise

- Multi-billion-dollar addressable market opportunity
- Invasive standard of care that may lead to blindness and loss of eye
- Clinical proof of concept with two routes of administration
- **Choroidal Melanoma:** Initiated activities for the global Phase 3 trial
- **Choroidal Metastasis:** Open IND and plan to initiate Phase 2 trial 2H 2023

Urologic Oncology Franchise

- Durable complete responses and improved survival in *in vivo* bladder cancer models
- Synergy with checkpoint inhibitors (durable immunologic memory)
- Ongoing enrollment of Phase 1 trial

Strong Cash Position

- Cash runway to fund operations into 2025

*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

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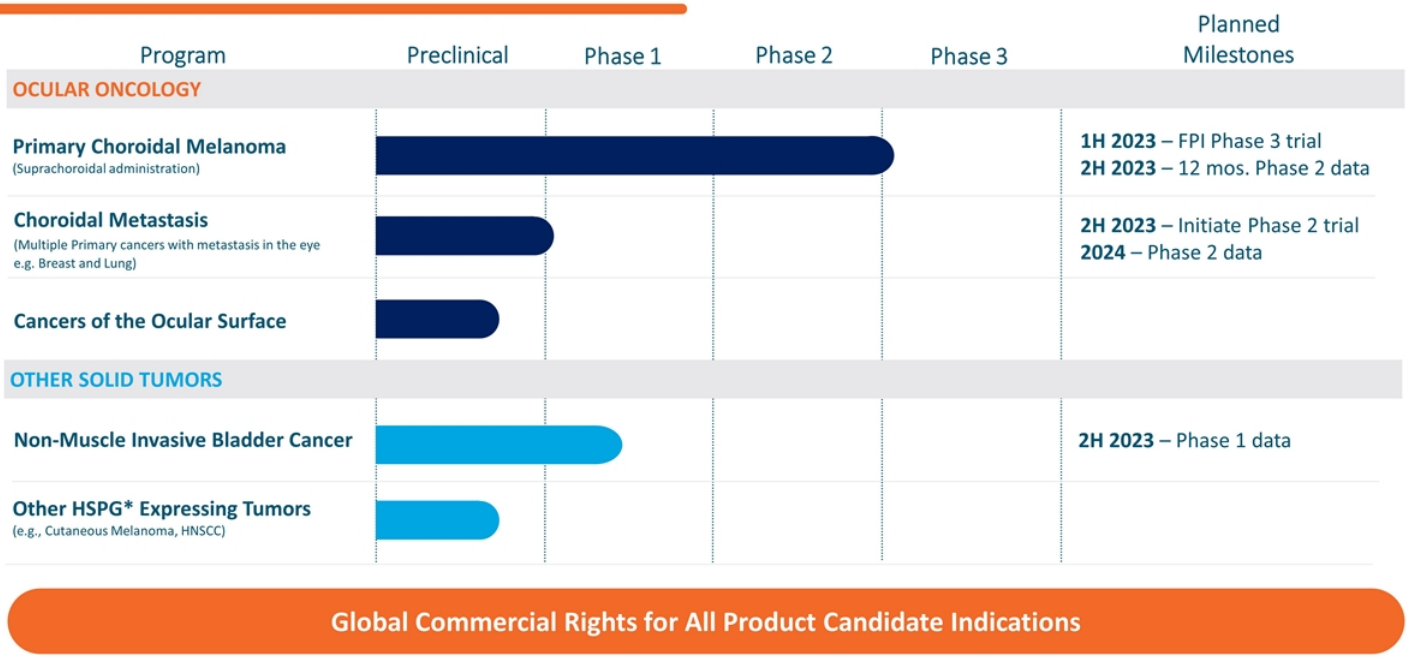
Pipeline Targeting Life-Threatening Cancers with High Unmet Needs



Global Commercial Rights for All Product Candidate Indications

*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

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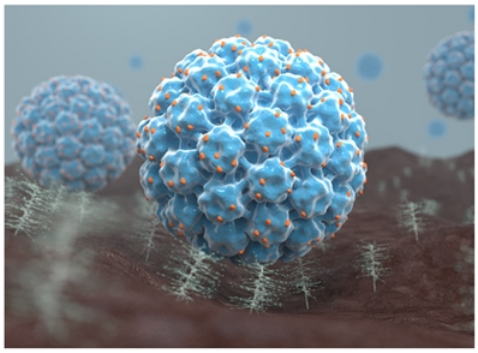
Targeted Oncology Platform: Virus-Like Drug Conjugates (VDCs)

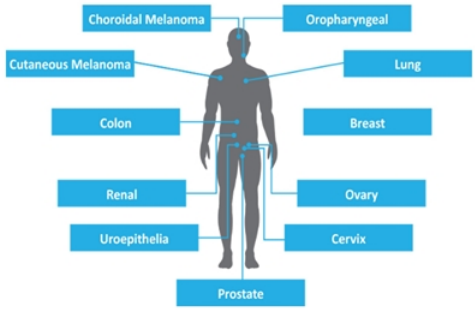
Virus-Like Particle Conjugated to a Cytotoxic Payload

Virus-Like Particle (VLP) | Cytotoxic Drug | Virus-Like Drug Conjugate (VDC)

Selective Binding to Tumor Associated HSPGs*



Potential Treatment of Multiple Solid Tumors



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

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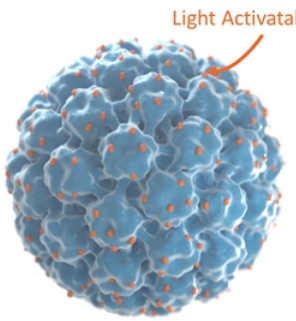
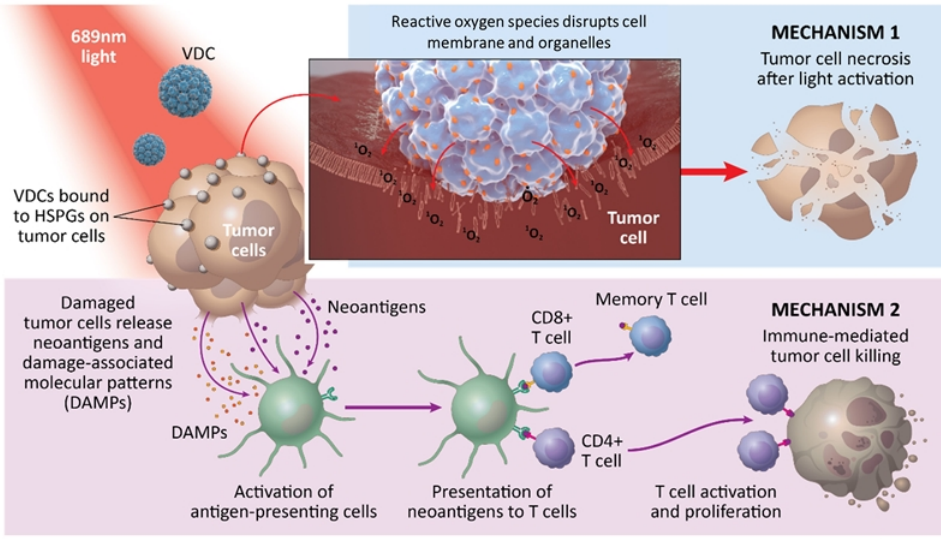
Bel-sar is a VDC with a Novel Dual Mechanism of Action



Bel-sar

Bel-sar is a novel VDC that consists of VLP conjugated to ~200 molecules of light activatable drug



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

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Ocular Oncology Franchise

Bel-sar
INN: belzupacap sarotalocan

Target Indications:

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

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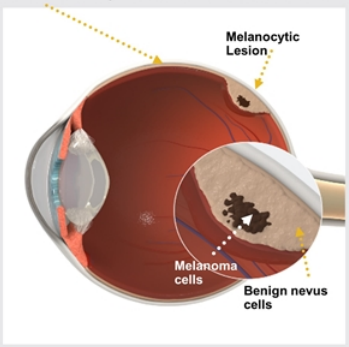
Primary Choroidal Melanoma – High Unmet Medical Need with No Drugs Approved

Most common primary intraocular cancer in adults

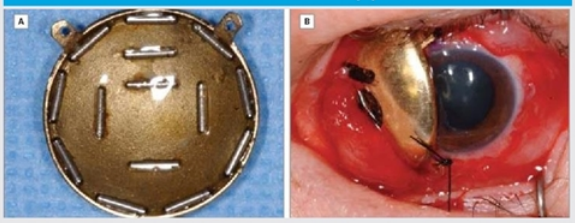
Impacts **11,000** patients in US/Europe per year

~80% patients diagnosed with early-stage disease

The choroid is the part of the uvea that is behind the retina



Standard of Care is Radiotherapy or Enucleation



Blindness, Eye Loss, and Disfiguration

Choroidal Melanoma is a Rare and Life-Threatening Ocular Cancer

Kaliki et al; Eye (Lond) 2017 Feb; 31(2): 241–257; Clearview & Putnam & Assoc. Market Research; Source: Peddada. J Contemp Brachytherapy. August 2019

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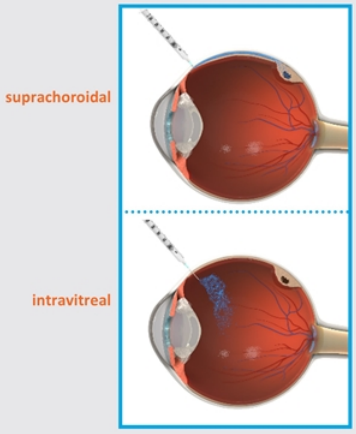
Bel-sar has the Potential to be the First Approved Therapy in Primary Choroidal Melanoma

Bel-sar is Delivered by Simple Intravitreal or Suprachoroidal Injection



Light Activation with Standard Ophthalmic Laser

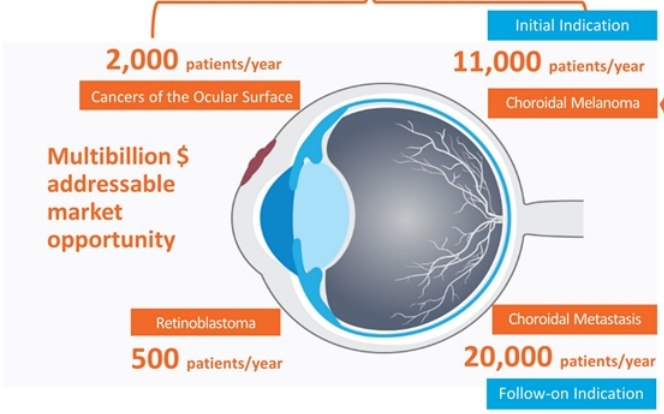
Goals of Treatment

- Local tumor control
- Preservation of vision
- No radioactive co-morbidities
- Opportunity to treat early and reduce risk of metastases
- Improvement in safety and quality of life

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

33,500

Ocular Oncology Franchise total addressable market



11,000

Choroidal Melanoma patients diagnosed each year (US/EU

~80%

of patients are diagnosed at the early stage (indeterminate lesions (ILs) and small tumors)

Current radiotherapy treatment

Leaves ~70% of patients with major irreversible vision loss within 5-10 years

~100

Ocular Oncologists in US/EU — focused call point

<20

Field Based Team
Intend to add small sales force to launch globally

ClearView & Putnam & Assoc. Epidemiology Analysis Choroidal Melanoma and Choroidal Metastasis
American Cancer Society- Retinoblastoma statistics
Batsi et al Cornea 2003 Ocular Surface squamous neoplasia: a review

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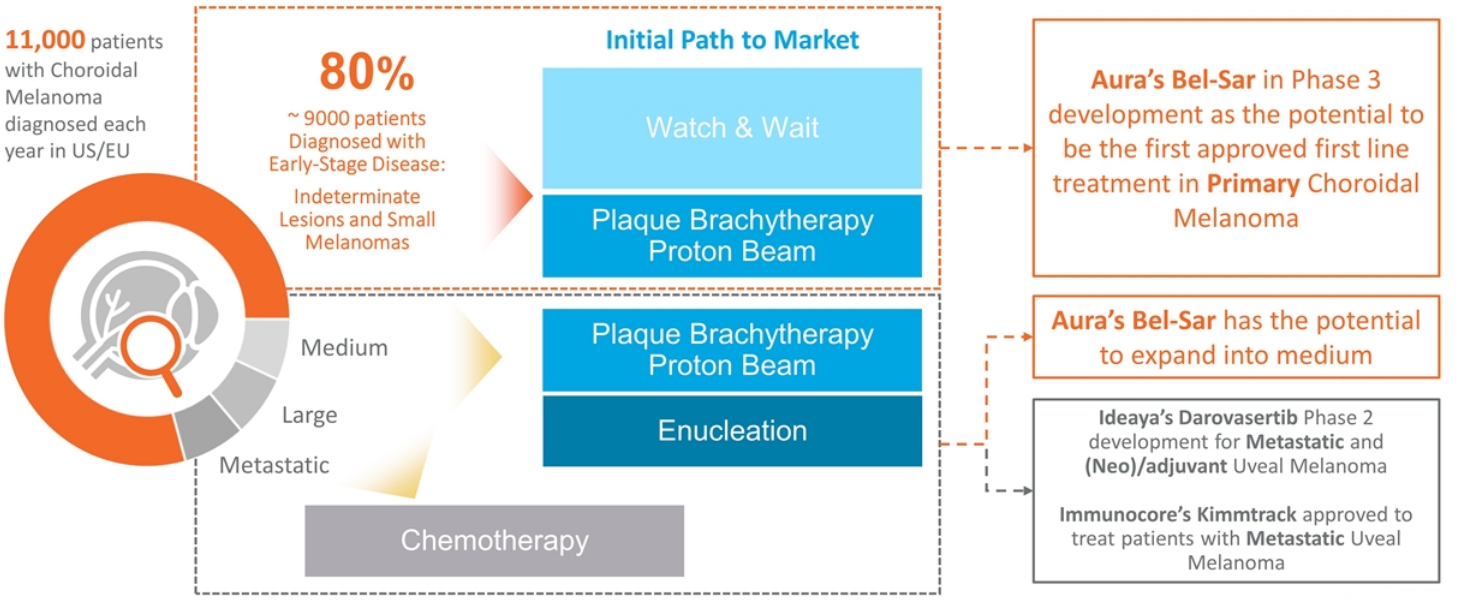
No Drugs Approved and No Known Competition in Early-Stage Disease



CM – Choroidal Melanoma

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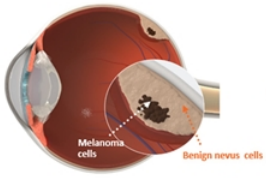
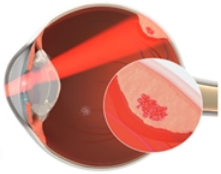
Goal for Bel-sar: Eliminate Malignant Cells in the Choroid and Preserve Vision

Similar to Current Clinical Practice with Radiotherapy - Local Tumor Control is Equivalent to a Local Cure



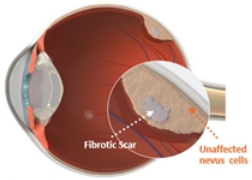
Baseline Measurement

Many early-stage melanomas have a small component of melanoma cells within a benign nevus



Treatment

Bel-sar targets mostly the malignant cells and not the benign nevus, retina or other ocular structures



Post-treatment Measurement

(Unchanged Tumor Height)

Malignant cells are replaced by fibrosis so there is a minimal reduction in size of the overall lesion after treatment

Key Endpoints Aligned with Clinical Practice and FDA

Endpoint	Endpoint Definitions
Tumor Progression	Growth in Tumor Height ≥0.5mm or ≥1.5 mm in Largest Basal Diameter (LBD)
Visual Acuity Failure	Decrease from baseline: ≥15 letters
Tumor Thickness Growth Rate	Change in tumor height over time

Objective of Treatment is to Obtain a Local Cure with Visual Acuity Preservation

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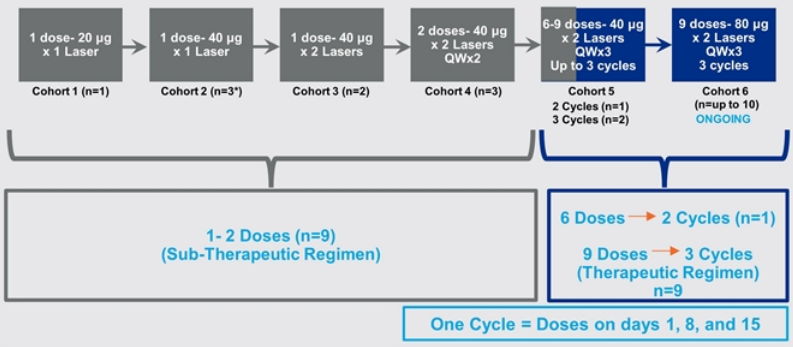
Ph 2 Trial - Evaluating Suprachoroidal Administration to Determine Optimal Administration Route

Enrollment Criteria

- Representative of Early-Stage Disease:
  - Indeterminate lesions and small choroidal melanomas
- Enrichment Strategy with active growth:
  - Tumor thickness ≥0.5 mm and ≤2.5 mm
  - LBD ≤10 mm
  - Active tumor growth (≥0.3mm) within 2 years of screening
  - Same criteria as the planned Phase 3

Ph2 SC Trial Design



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

*2 subjects were planned; third subject was additionally enrolled due to dose error in 1 subject
ClinicalTrials.gov Identifier: NCT04417530 ; AU-011-202

SC – Suprachoroidal; LBD – Largest Basal Diameter

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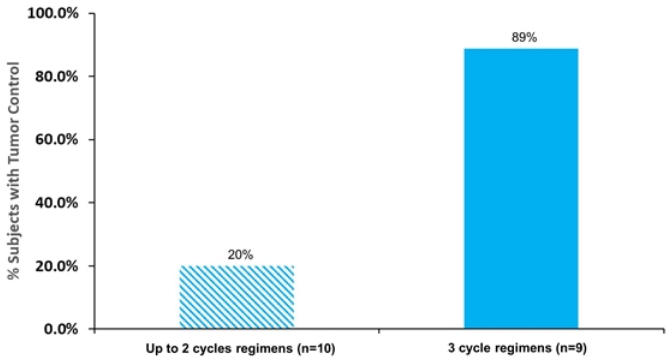
Ph 2 Interim Tumor Control Rates Demonstrated a Dose Response

Dose Response: Lower Regimens vs. 3 Cycle Regimens



Tumor Progression: change from baseline in thickness ≥0.5mm; or in LBD ≥1.5mm confirmed by at least one repeat assessment

Interim Data- January 10, 2023

Average 8-10 Months of Follow Up

Populations	Total Patients (n)	Tumor Control Rate	Average Follow-up (months)
All Doses/Regimens			
All Treated Patients	20	55% (11/20)	9
Lower Doses/Regimens			
Up to 2 Cycles (20µg-40µg)	10	20% (2/10)	10
Highest Doses/Regimens*+			
3 Cycles (n=9) 40µg (n=2)/80µg (n=7)	9	89% (8/9)	8

*One subject in C6 who discontinued after 1 cycle due to unrelated SAEs is not included
+Assigned regimen of 3 cycles (Cohort 6) and Cohort 5 subjects who received 3 cycles, each cycle comprised of 3 once/week treatments of 40µg x 2 Laser or 80µg x 2 Laser
Lower dose regimens (n=10) include cohorts 1-4 and 1 patient in Cohort 5 that received 2 cycles

Dose Response Observed with Interim Tumor Control Rates Demonstrated Meaningful Clinical Benefit

LBD – Largest Basal Diameter

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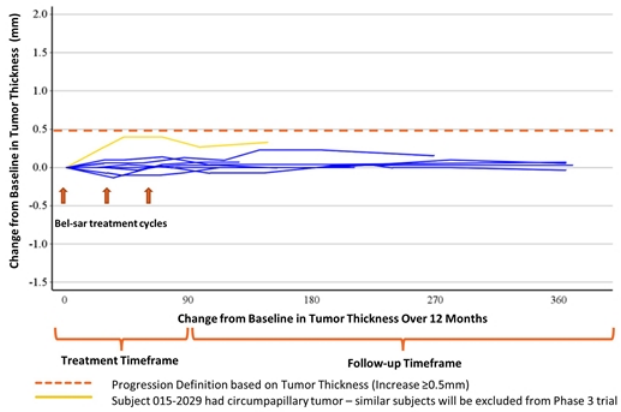
Ph 2 Interim Analysis Demonstrated Tumor Control Rate 89%-100%

89%-100% Tumor Control Rate: Active Growth and Therapeutic Regimen (3 cycles)



Tumor Progression: change from baseline in thickness ≥0.5mm; or in LBD ≥1.5mm confirmed by at least one repeat assessment; Interim Data- January 10, 2023; post-SOC data not included

Average 8-9 Months of Follow Up

Populations	Total Patients (n)	Tumor Control Rate	Average Follow-up (months)
Highest Doses/Regimens			
3 Cycles (n=9) 40µg (n=2)/80µg (n=7)	9	89% (8/9)	8
Highest Doses/Regimens - Planned Phase 3^			
3 Cycles (n=8) 40µg (n=2)/80µg (n=6)	8	100% (8/8)	9

One subject in C6 who discontinued after 1 cycle due to unrelated SAEs is not included
Assigned regimen of 3 cycles (Cohort 6) and Cohort 5 subjects who received 3 cycles, each cycle comprised of 3 once/week treatments of 40µg x 2 Laser or 80µg x 2 Laser
^ One subject in C6 with circumpapillary tumor not included (similar subjects not planned in Phase 3 trial)

Ph 2 Interim Analysis Demonstrated Tumor Control Rate of 100% in Planned Ph 3 Population^

Ph 2 Interim Analysis Demonstrated Visual Acuity Preservation ~90%

Vision Preservation Rates					
Populations	**Total Patients (n)**	**Vision Failures (n)**	**Vision Preservation Rate**	**Mean Change from Baseline at Last Visit** (letters)	**Average Follow-up** (months)
All Dose Cohorts					
All Treated Patients	20	2	90%	-3.7	9
Lower Doses/Regimens					
Up to 2 cycles (20µg-40µg)	10	1	90%	-3.2	10
Highest Doses/Regimens*+					
3 Cycles (40µg-80µg) 40µg (n=2)/80µg (n=7)	9	1	89%	-4.8	8
Highest Doses/Regimens - Planned Phase 3*+					
3 Cycles (40µg-80µg)^ 40µg (n=2)/80µg (n=6)	8	1	88%	-5.3	9

*One subject in C6 who discontinued after 1 cycle due to unrelated SAEs is not included
+Assigned regimen of 3 cycles (Cohort 6) and Cohort 5 subjects who received 3 cycles, each cycle comprised of 3 once/week treatments of 40µg x 2 Laser or 80µg x 2 Laser
Vision Failure confirmed loss ≥15 letters at ≥Week 39; post-SOC data not included
^7 out of 8 subjects in this subgroup were high-risk for vision loss (tumor edge ≤ 3 mm from the foveola or optic disc)
Interim Data- January 10, 2023

Interim Data Demonstrated High Vision Preservation Rates Across All Groups Including Patients at High Risk for Vision Loss

SC – Suprachoroidal

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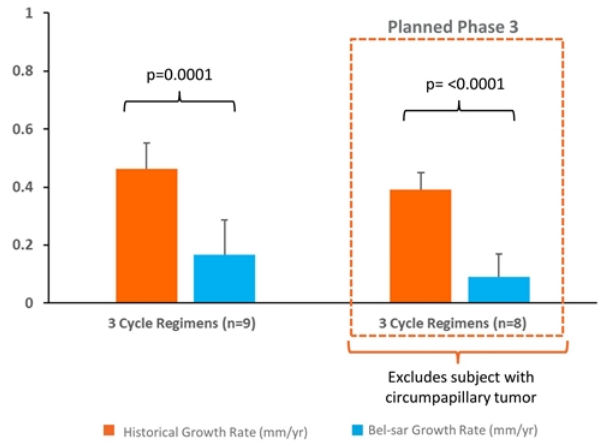
Ph 2 Interim Data Demonstrated Statistically Significant Tumor Growth Rate Reduction

Statistically Significant Change in Tumor Growth Rate (mm/yr): Therapeutic Regimen (3 cycles)



Change in Tumor Growth After Treatment with Bel-sar

	n	Historical Growth Rate (mm/yr)	AU-011 Growth Rate (mm/yr)	Growth Rate Reduction (mm/yr)	p-value	Average Follow up (months)
Highest Doses/Regimens						
3 Cycles (40µg-80µg) 40µg (n=2)/80µg (n=7)	9	0.454	0.169	-0.285	0.0001	8
Highest Doses/Regimens - Planned Phase 3^						
3 Cycles (40µg-80µg) 40µg (n=2)/80µg (n=6)	8	0.382	0.093	-0.289	<0.0001	9

Tumor thickness growth rates/ slopes estimated using MMRM (random intercept and slope model for Hx and Study periods)

One subject in C6 who discontinued after 1 cycle due to unrelated SAEs is not included
Assigned regimen of 3 cycles (Cohort 6) and Cohort 5 subjects who received 3 cycles, each cycle comprised of 3 once/week treatments of 40µg x 2 Laser or 80µg x 2 Laser
^One subject in C6 with circumpapillary tumor not included (similar subjects not planned in Phase 3 trial)

Interim Data Showed Growth Arrest in Planned Phase 3 Population with a p-value of <0.0001

Ph 2 Ongoing Tolerability Evaluation Continues to Be Favorable

No Grade 3 AEs and Majority of AEs Were Transient and Resolved Without Clinical Sequelae

Ongoing Phase 2 Safety Outcomes with SC Administration

All Treated Subjects (n=20) Drug/Laser Related Adverse Events ≥10% Subjects	Grade I	Grade II	Grade III	Total
Anterior Chamber Cell/ Inflammation	25%	0	0	**25%**
Conjunctival Hyperemia	15%	0	0	**15%**
Eye Pain	10%	5%	0	**15%**
Punctate Keratitis	10%	0	0	**10%**

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

Interim Data- January 10, 2023

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%**	~10%

Serious Adverse Event	Radiotherapy*	Bel-Sar+
Scleral Necrosis	**0-5%**	**0%**
Enucleation/Eye Loss	**10-15%**	**0%**
Vision Loss in High-Risk Subjects (≥30 letters)**	**~90%**	**0%++**

*Cross-trial comparison of Radiotherapy and AU-011-202
+Related to bel-sar or laser
++75% (15/20) of patients in Ph2 SC trial were at high risk for vision loss

Tolerability Profile Supports Indication as a First Line Treatment in Early-Stage Disease

*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 Subjects are those with tumors <3mm to fovea or optic nerve
Bel-Sar – Belzupacap Sarotalocan

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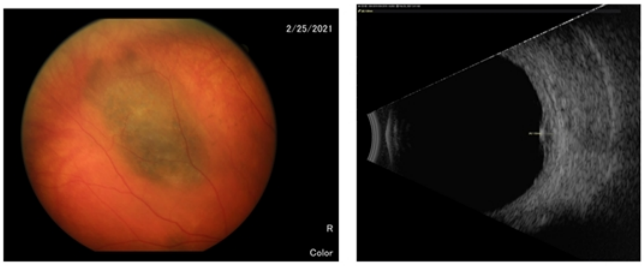
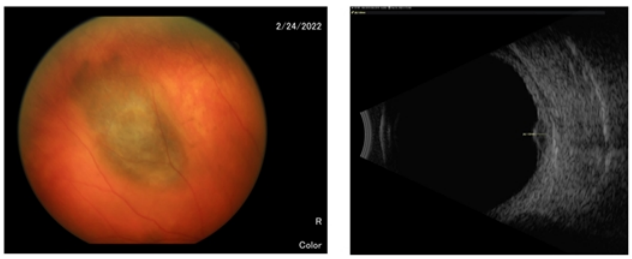
Durable Response to Treatment with Tumor Control & Vision Preservation at 1 Year, with 3 Cycles



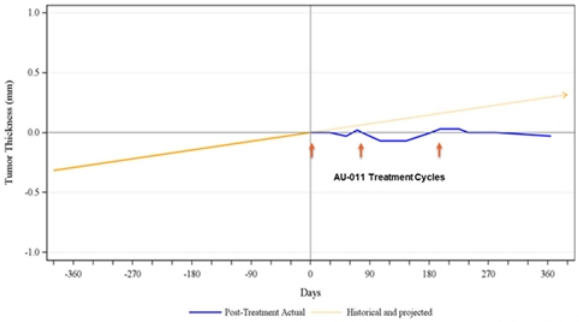
Photograph and ultrasound at baseline
TT: 1.50 mm, LBD: 8.92 mm (IRC reads)



Photograph and ultrasound at 12 months
TT: 1.47 mm, LBD: 8.55 mm (IRC reads)

Cohort 5 Subject with Documented Tumor Growth
Tumor location: Superotemporal

	Baseline	Week 4	Week 8	Week 12	Week 26	Week 39	Week 52
BCVA (letter score)	91	92	92	89	89	90	89



BCVA: best corrected visual acuity; IRC: independent reading center; LBD: largest basal diameter; TT: tumor thickness; AU-011= Bel-sar

Historical and projected growth based on MMRM

Randomized Controlled Global Phase 3 Trial

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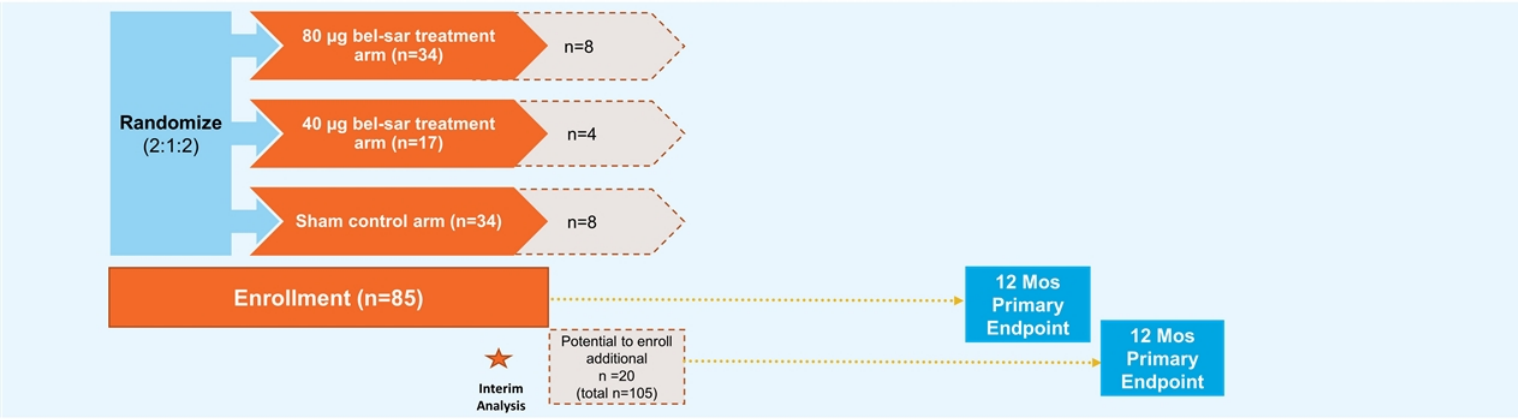
Global Phase 3 Trial Design Using Suprachoroidal Administration

Fast Track and Orphan Designations



Primary Endpoint

- Composite time to event analysis:
  - Tumor progression or visual acuity failure between Intervention Group (High Dose) and Sham Group

Key Secondary Endpoints

- Time to Tumor Progression
- Tumor Growth Rate over 52 weeks

Adaptive Design with Conservative Assumptions Optimizes Probability of Success

Bel-Sar – Belzupacap Sarotalocan; LSLV- last subject last visit

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Clinical Endpoints to Support Approval in Alignment with Regulatory Agencies

Composite Endpoint

Endpoint	Endpoint Assumptions	Endpoint Definitions
Tumor Progression	**Bel-sar:** 35% Tumor Progression **Sham:** 85% Tumor Progression	Growth in Tumor Height ≥0.5mm or ≥1.5 mm in Largest Basal Diameter
Vision Acuity Failure	**Bel-sar:** 15% VA Failure **Sham:** 2% VA Failure	Decrease from baseline: ≥15 letters
Tumor Thickness Growth Rate	Bel-sar vs Sham : -0.28mm/year reduction	Change in tumor height over time

Conservative Assumptions Provide >90% Power to Maximize Probability of Success with Single Global Phase 3 Trial

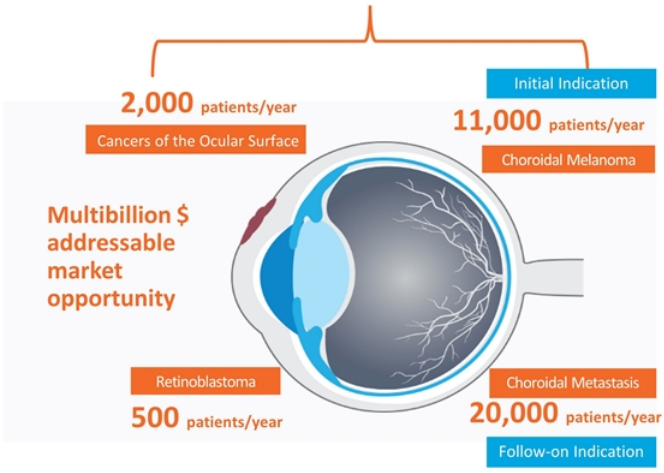
Note: Tumor Height (TH) is synonymous with Tumor Thickness; VA – Visual Acuity; Bel-sar – Belzupacap Sarotalocan

Choroidal Metastasis

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

33,500

Ocular Oncology Franchise total addressable market



20,000

Choroidal Metastasis patients diagnosed each year (US/EU)

2x

Doubles the market opportunity

Same Call Point as CM

~100 Ocular Oncologists in US/EU — focused call point

Same Field Force as CM

<20 Field Based Team

Intend to add small sales force to launch globally

ClearView & Putnam & Assoc. Epidemiology Analysis Choroidal Melanoma and Choroidal Metastasis
American Cancer Society- Retinoblastoma statistics
Batsi et al Cornea 2003 Ocular Surface squamous neoplasia: a review

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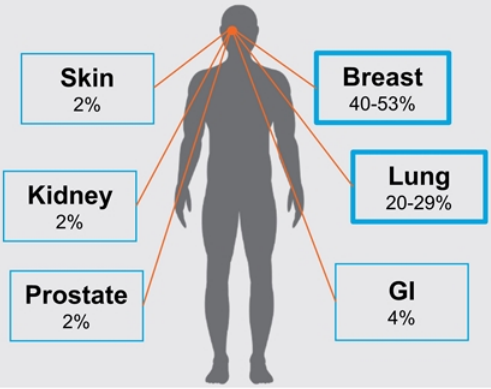
Choroidal Metastasis is a High Unmet Medical Need

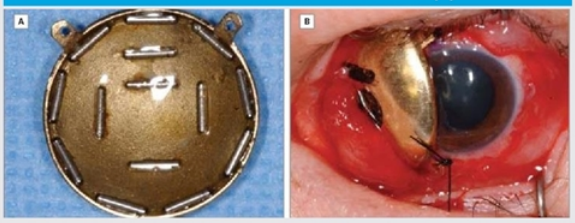
Originate from **Multiple Primary** Cancers
(e.g. Breast and Lung)

20,000/year eyes diagnosed in US

88% with choroidal location
72% unilateral and solitary



Standard of Care is Radiotherapy



Blindness, Eye Loss, and Disfiguration

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).

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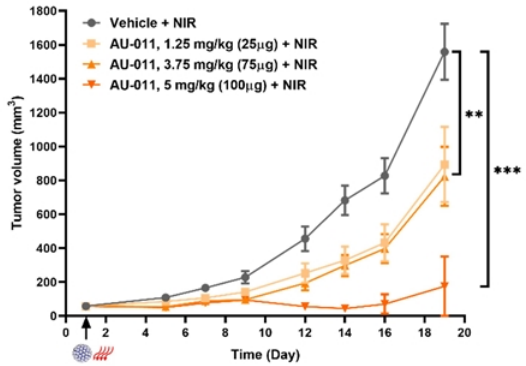
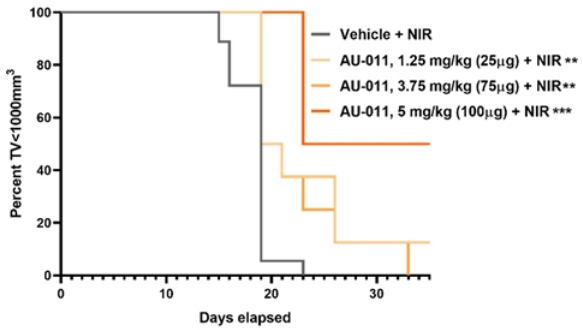
Bel-sar has Demonstrated Dose-Dependent Activity for Cancer Types Known to Metastasize to the Choroid

Breast Cancer In-Vivo (Syngeneic Mouse Model, EMT-6)

Tumor Regression



Prolonged Survival



Tumor cells were implanted subcutaneously. AU-011 treatment was initiated when tumors reached approximately 50 mm^3. Treatment consisted of a single intravenous administration of AU-011 followed 12 hours later by light activation (400 mW/cm^2, 58 J/cm^2). Tumor volumes were measured over time (N=8-12)

Single Administration of Bel-sar Showed Tumor Regression and Prolonged Survival in a Dose-Dependent Fashion
Data Supportive of Moving into Phase 2 Trial 2H 2023

Savinainen et al., ARVO 2022 Abstract # 3709397; AU-011 – Bel-sar – Belzupacap Sarotalocan

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Urologic Oncology

Bel-sar
INN: belzupacap sarotalocan

Target Indications:

Non-Muscle Invasive Bladder Cancer

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Bel-Sar is a Clinical Asset with a Multibillion Dollar Market Opportunity in Non-Muscle Invasive Bladder Cancer

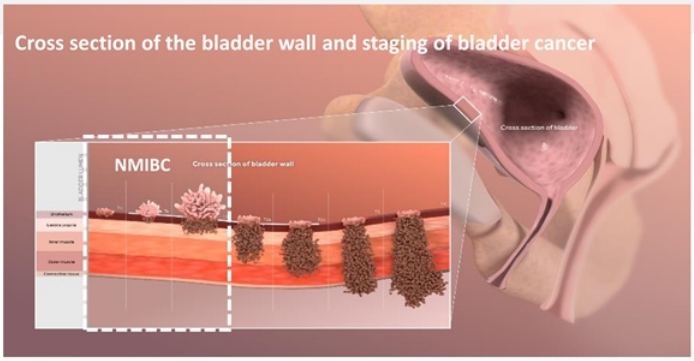
NMIBC is High Unmet Need	- High Incidence globally >500,000 patients/year - Rate of recurrence is high
Bel-Sar's MoA Well Suited to NMIBC	- Strong precedent for immune-activators in NMIBC (BCG) - Bladder tumors physically accessible via cystoscope (injection, laser)
Robust Nonclinical Data Package	- Durable CRs and improved survival in *in vivo* bladder cancer models - Synergy with checkpoint inhibitors (durable immunologic memory)
Read Through from Ocular Clinical Proof of Concept	- Two clinical trials demonstrate robust efficacy in Ocular Oncology - Initiating global Ph 3 study in choroidal melanoma
Phase 1 Study Ongoing	- Initial data available in 2H 2023

CR – complete responses; BCG - Bacillus Calmette–Guérin

NMIBC is a High Unmet Need with High Recurrence Rate

573,000
New cases NMIBC/year globally

81,000
New cases/year in the US



Risk Stratification	Treatment Guidelines	Problem
Low Risk (40%)	Surveillance or TURBT + Chemo	Recurrence after TURBT
Intermediate Risk (30%)	Mix of TURBT + Chemo / BCG	Failure of BCG/Chemo ~40%
High Risk (30%)	Mix of Chemo / BCG	Progression with no alternative option but Cystectomy

Mechanism of Action Supports Bel-sar Opportunity as Potential Front-Line Treatment Following Initial Diagnosis and/or BCG Refractory Disease

Source: Putnam Associates Primary Research & Literature Review, July 2021; NMIBC – Non-Muscle Invasive Bladder Cancer; TURBT - trans urethral resection of bladder tumor; BCG - Bacillus Calmette–Guérin; Bel-sar – Belzupacap Sarotalocan

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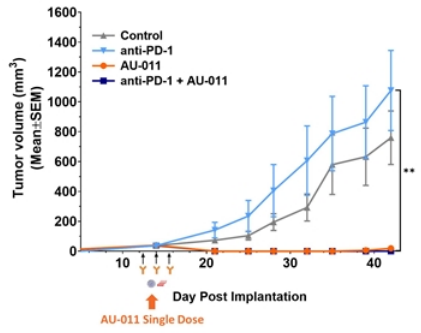
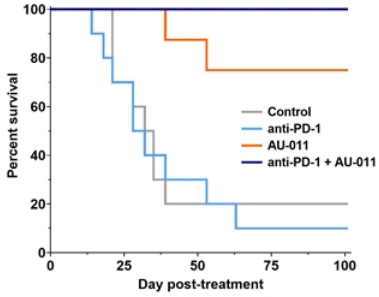
Durable CRs with Single Administration of Bel-sar in Bladder Cancer Model

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

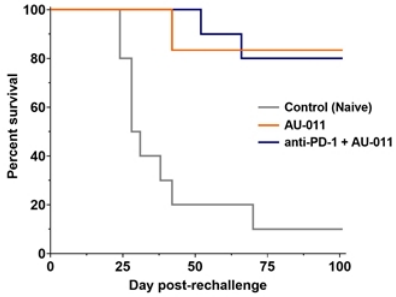
Tumor Regression



Survival



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

Bel-sar: Belzupacap Sarotalocan; CR: Complete Responses

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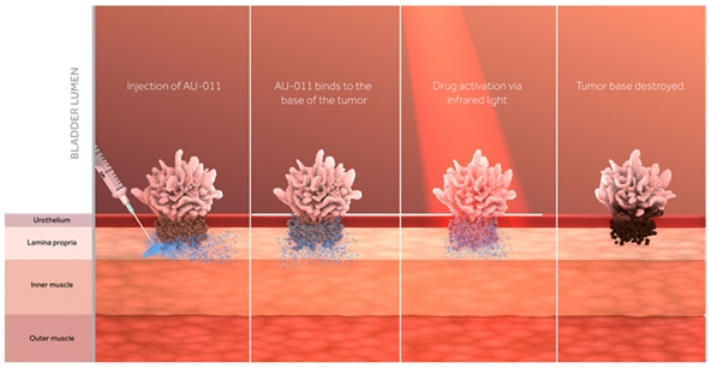
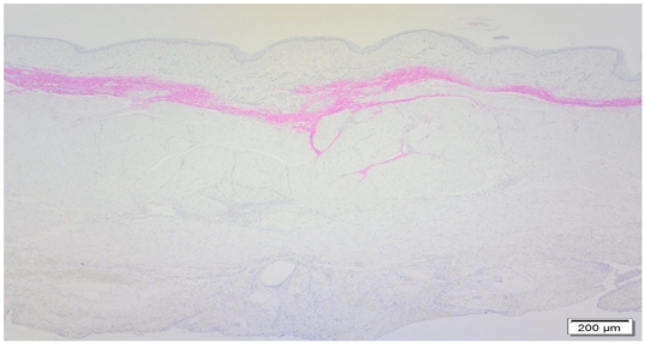
Novel Approach using Intra-mural Administration

Intra-mural Administration



Bel-sar will be administered in the lamina propria close to the base of the tumor

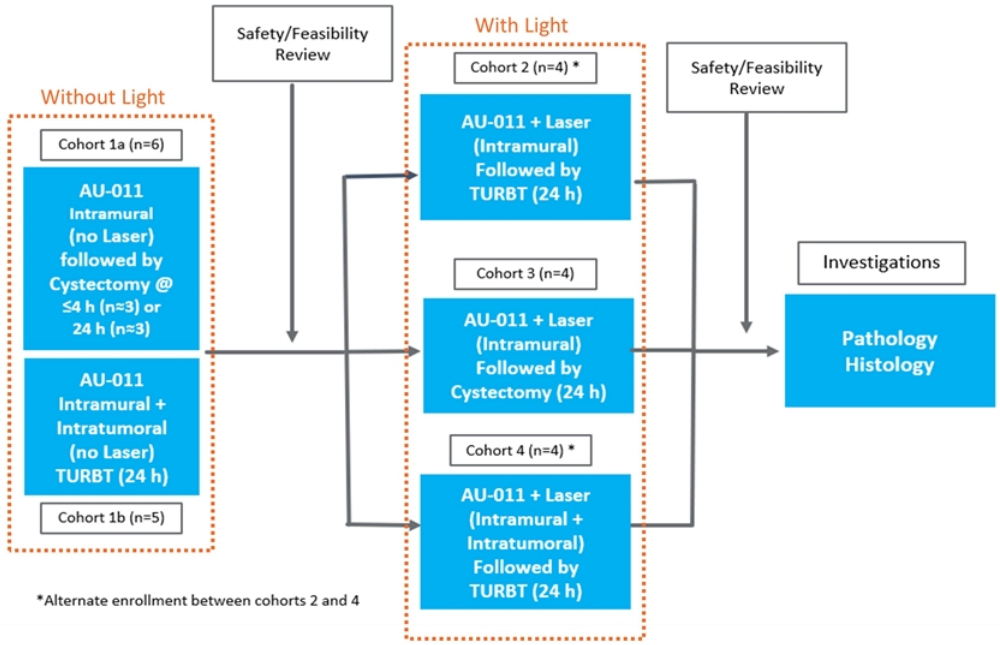
Distribution Into the Mucosal Layer Into the Bladder Wall



3 Hour Post AU-011 Injection (Dog tox study):
Bel-Sar positive staining (pink) extends laterally at the junction between the submucosa and superficial muscularis of the bladder

Ongoing Phase 1 Trial Designed to Establish Safety, and Optimize Administration in Intermediate and High Risk NMIBC Patients

Ongoing Ph 1 Trial Evaluating Bel-sar Distribution, Local Necrosis and Evidence of Immune Activation



Bel-sar, AU-011 – Belzupacap Sarotalocan

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Strategy & Key Milestones

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Aura Biosciences Investment Highlights

Technology Platform

Virus-like Drug Conjugates

- Novel class of cancer therapies - tumor specific cytotoxicity combined with immune activation
- Targeting multiple solid tumor indications initially focusing on ocular and urologic cancers

Clinical Data Highlights

Ocular Oncology Franchise:

- Positive data in completed Phase 1b/2 trial (IVT)
- Positive interim data in ongoing Phase 2 trial (SC)
- Initiated activities for the global Phase 3 trial

Urologic Oncology Franchise:

- Enrolling patients in Phase 1 trial in NMIBC

2023 Milestones

Primary Choroidal Melanoma:

- 1H 2023: Dose first patient in global Phase 3 trial
- 2H 2023: Phase 2 SC Data

Choroidal Metastasis:

- 2H 2023: Initiate activities for Phase 2 trial

Non-Muscle Invasive Bladder Cancer:

- 2H 2023: Interim Phase 1 data

Key Highlights

Strong Phase 2 Clinical Proof of Concept

Phase 3 Ready Clinical Asset

Multi-Billion Dollar Market Opportunity

Strong Cash Position

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Appendix: Phase 1b/2 IVT Trial

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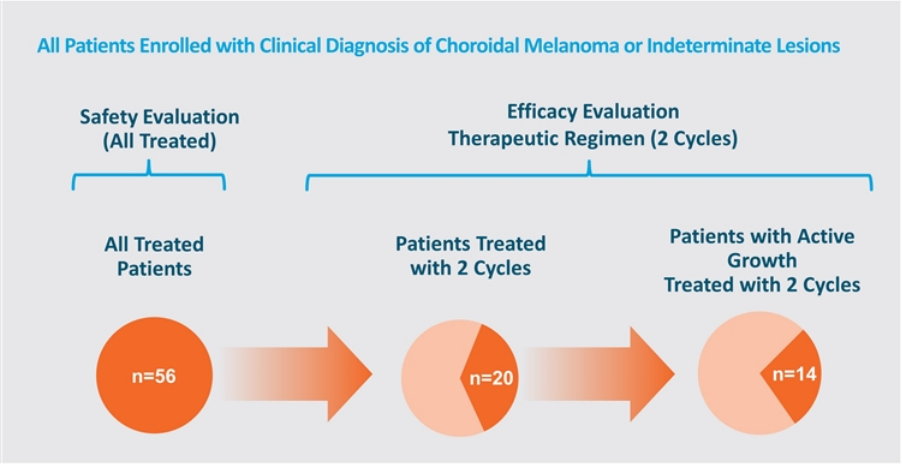
Phase 1b/2 IVT – Key Patient Populations and Objectives



Primary Objective: Safety

- Drug or treatment related adverse events (AEs) / serious adverse events (SAEs)

Secondary Objective: Efficacy

- Tumor thickness growth rate before and after treatment
- Local tumor control
- Visual acuity preservation

Enrichment Strategy to Enroll Subjects with Actively Growing Tumors Provides Important Insight into How Bel-sar May Perform in Phase 3 Trial

Phase 1b/2 – Demonstrated Favorable Tolerability Profile

Majority of AEs Were Transient and Resolved Without Clinical Sequelae

AU-011 Treatment Related AEs ≥15% Subjects (n=56) Final	Grade I/II	Grade III
Vitreous Inflammation	83.9%	7.1%
Anterior Chamber Inflammation	67.9%	3.6%
Increase in Intraocular Pressure	46.4%	0
Pigmentary Changes/Peritumoral	37.5%	0
Keratic Precipitates	23.2%	0
Floaters/Vitreous Opacity	19.7%	1.8%
Decreased visual acuity	19.6%	1.8%

Treatment Related SAEs (n=56)	
Vision Loss (juxtafoveal tumor, n=2)	3.6%

SAE of vision loss in two subjects with tumors close to fovea due to pigmentary changes at the edge of the tumor
SAEs are listed separately in the SAE table Completed Ph 1b/2 IVT trial (AU-011-101)

Adverse Event	Radiotherapy*	Bel-Sar
Surgeries secondary to AEs (e.g., Cataracts)	40%+	~13%
Radiation Retinopathy	40%+	0%
Neovascular Glaucoma	10%	0%
Dry Eye Syndrome	20%	~2%
Strabismus	2%+	0%
Retinal Detachment	1-2%	~2%
Vision Loss (≥15 letters)	~70%	~21%

Serious Adverse Event	Radiotherapy*	Bel-Sar
Scleral Necrosis	0-5%	0%
Enucleation/Eye Loss	10-15%	0%
Vision Loss in High-Risk Subjects** (≥30 letters)	~90%	4.6%⁺

Cross-trial comparison of AU-011-101 and Radiotherapy ⁺77% (43/56) of patients in Ph1b/2 IVT trial were at high risk for vision loss ; 2/43= 4.6%

Tolerability Profile Supports Indication as a First Line Treatment in Early-Stage Disease

*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 Subjects are those with tumors <3mm to fovea or optic nerve
Bel-Sar – Belzupacap Sarotalocan

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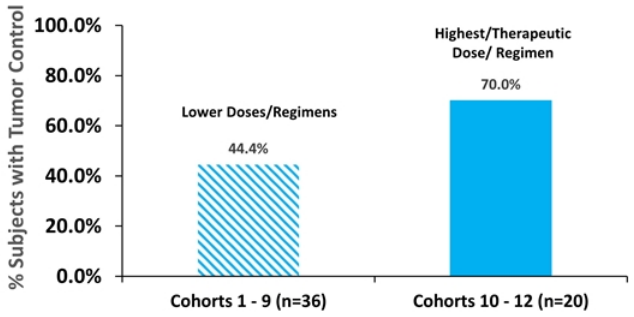
Phase 1b/2 IVT- 70% Tumor Control Rate and Statistically Significant Growth Rate Reduction

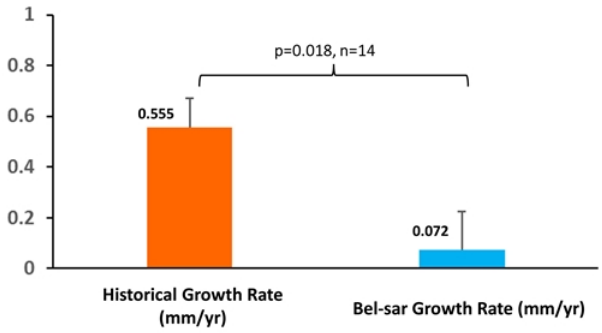
Tumor Control Rates at 12 months



Cohorts 1-9 include single dose escalation cohorts and multiple dose escalation cohorts up to 1 cycle of treatment; Cohorts 10-12 include 2 cycles of treatment at the highest dose

Completed Ph1b/2 IVT trial (AU-011-101)

Change in Tumor Growth Rate



- Disease-modifying effect supports tumor is inactive and malignant cells have been targeted by bel-sar

Positive Data in Two Efficacy Endpoints in Patients with Early-Stage Choroidal Melanoma

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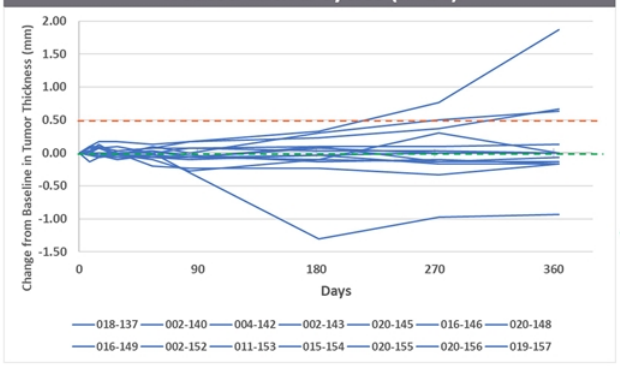
Phase 1b/2 – 64% Patients with Active Growth Achieved Tumor Control when Treated with Therapeutic Regimen

All Patients with Active Growth Treated with 2 Cycles (n=14)



Change from Baseline in Tumor Thickness Over 12 Months

Progression Definition Tumor Height Increase >0.5mm

Completed Ph1b/2 IVT trial (AU-011-101)

Tumor Control Rate at 12 months

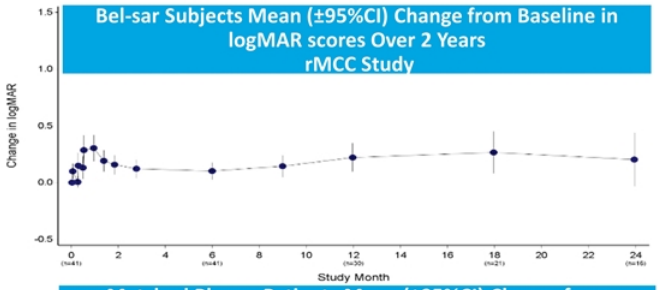
Populations	Total Patients (n)	**Tumor Control Rate (at 12 months)**
Therapeutic Dose/Regimen (2 Cycles)		
All Patients Treated with 2 Cycles	20	70% (14/20)
All Patients with Active Growth Treated with 2 Cycles	14	64% (9/14)

Tumor control failure (progression): Growth from baseline in Tumor Height >0.5mm or LBD >1.0mm due to definitive Tumor Growth (ie, not judged by the Investigator to be due to inflammation/swelling, hemorrhage or pigmentary changes) and not treated with standard of care

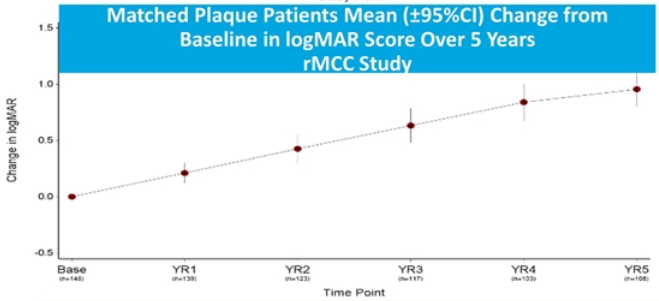
We Believe Results Support Bel-sar as First Line Treatment to Help Many Patients Avoid the Need for Radiotherapy

Visual Acuity was Preserved in Majority of Patients with IVT Administration of Bel-sar

Bel-sar Subjects Mean (±95%CI) Change from Baseline in logMAR scores Over 2 Years rMCC Study



Matched Plaque Patients Mean (±95%CI) Change from Baseline in logMAR Score Over 5 Years rMCC Study



Vision Preservation Rates
Phase 1b/2 IVT Study
Follow up 12 months

Populations	Total Patients (n)	Vision Preservation Rate Failure: Long-term loss ≥15 letters
All Dose Cohorts		
All Treated Patients	56	86% (48/56)
Patients with Active Growth - High Risk for Vision Loss	17	76% (13/17)
Therapeutic Regimen (2 cycles)		
All Treated Patients	20	75% (15/20)
Patients with Active Growth	14	71% (10/14)

1 patient had loss ≥15 letters at Week 52 visit which recovered within 15 letters at the next visit which was ~3 weeks after standard of care (SOC); all other post-SOC data excluded for all subjects
Completed Ph1b/2 IVT trial (AU-011-101)

Vision was Preserved in Majority of Patients
Whereas Radiotherapy Often Leads to Irreversible and Long-Term Severe Vision Loss

Bel-sar – Belzupacap Sarotalocan

Retrospective Match Case Control Study (rMCC) to evaluate visual acuity outcomes of bel-sar vs radiotherapy. Matching performed by independent statistician.. 43 bel-sar patients with HRVL were matched to 150 radiotherapy patients.

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