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): November 6, 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)**	**(IRS Employer Identification No.)**

80 Guest Street **Boston, Massachusetts**		**02135**
(Address of Principal Executive Offices)		**(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))

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

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

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. ☐

Item 7.01. Regulation FD Disclosure.

AAO 2023 Annual Meeting Data Release

On November 6, 2023, Aura Biosciences, Inc. (the "Company") presented positive clinical efficacy updates of belzupacap sarotalocan ("bel-sar") for early stage choroidal melanoma ("CM") with suprachoroidal ("SC") administration at the American Academy of Ophthalmology ("AAO") 2023 Annual Meeting. The Company issued a press release announcing these and other updates titled "Aura Biosciences Receives FDA Agreement Under Special Protocol Assessment (SPA) for CoMpass Phase 3 Clinical Trial of Belzupacap Sarotalocan (Bel-sar) in Early-stage Choroidal Melanoma." A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

In connection with these updates, the Company updated its corporate presentation for use in meetings with investors, analysts and others. A copy of the corporate presentation is furnished herewith as Exhibit 99.2 and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibits 99.1 and 99.2 hereto, 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.

AAO 2023 Annual Meeting Data Release

On November 6, 2023, the Company announced that it has received agreement from the United States Food and Drug Administration ("FDA") under a Special Protocol Assessment ("SPA") for the design and planned analysis of CoMpass, the Company's global Phase 3 clinical trial of bel-sar for the first-line treatment of adult patients with early-stage CM. The Company also announced the presentation of positive Phase 2 safety and efficacy data of bel-sar with 90% of patients at twelve months of follow-up evaluating two key clinical endpoints: tumor control and visual acuity preservation using SC route of administration for the first-line treatment of adult patients with early-stage CM. The results were presented at the AAO 2023 Annual Meeting, in San Francisco, California.

The Company received written agreement from the FDA under an SPA for the design and planned analysis of the Global Phase 3 CoMpass trial indicating concurrence by the FDA with the adequacy of the study, if successful, to address the objectives necessary to support the Company's planned biologics license application submission. The Phase 3 trial is designed as a superiority trial comparing bel-sar versus sham. The trial is a global, multi-center, masked study, and it is intended to enroll approximately 100 patients randomized 2:1:2 to receive high dose regimen of bel-sar with SC administration, low dose regimen of bel-sar with SC administration, or a sham control. The primary endpoint is time to tumor progression, and the first key secondary endpoint is a composite time to event analysis that will compare the tumor control and visual acuity of the bel-sar high dose regimen to sham when the last patient completes their 15 months of follow up. The trial is powered at greater than 90%. The Company is on track to dose the first patient in the fourth quarter of 2023.

The Phase 2 trial 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 CM. A total of 22 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=16). Cohorts 5 and 6 (n=13) 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=10) 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 in the analysis. All patients in Cohorts 5 and 6 had active tumor 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 control, visual acuity preservation and tumor growth rate as the defined clinical endpoints to evaluate preliminary efficacy. The results, with 90% of patients at twelve months of follow-up who received three cycles of therapy in Cohorts 5 and 6, and who match the criteria for the global Phase 3 trial, showed a tumor control rate of 80% (8/10) and the visual acuity preservation rate was 90% (9/10). The majority of patients being at high-risk for vision loss with tumors close to the fovea or optic disk. For the 80% of patients that responded, data showed a statistically significant reduction in tumor growth rate (-0.382 mm/yr, $p = <0.0001$) compared to each patient's documented growth rate at study entry. The overall tolerability profile of bel-sar was favorable, with no dose-limiting toxicities, treatment-related SAEs or significant AEs reported as of August 3, 2023. There was no posterior inflammation and only mild anterior inflammation (Grade 1) in approximately 18% of the patients which was self-limited or resolved with a short course of topical steroids. Treatment-related AEs were predominantly mild and resolved without sequalae. The Company believes these updated 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 at an early stage and have no approved therapies to date.

Preliminary Data from Phase 1 Trial in Bladder Cancer

On November 6, 2023, the Company announced in a press release that the ongoing Phase 1 trial has completed enrollment of the cohort that received bel-sar injection without light activation. Protocol mandated safety review found no safety issues and the study has proceeded to the bel-sar injection plus light activation cohorts. Preliminary data from the first patient in the light activated cohort of the trial, utilizing a single dose of bel-sar with light activation, demonstrated a clinical complete response demonstrated by absence of cancer cells on histopathology with evidence of extensive necrosis and immune activation.

Bel-sar is a novel investigational agent designed with a dual mechanism of action that includes targeted cytotoxicity and immune activation. The ongoing Phase 1 multi-center, open-label clinical trial is expected to enroll approximately 19 adult patients. The trial is designed to assess the safety and tolerability of bel-sar as a single agent. The trial will provide histopathological evaluation after the local treatment to assess bel-sar's biological activity. In addition, the FDA has allowed an amendment to the protocol of the Company's ongoing Phase 1 trial evaluating bel-sar, allowing the inclusion of adult patients with muscle invasive bladder cancer ("MIBC") in addition to non-muscle invasive bladder cancer ("NMIBC"). The Company expects to provide more data in mid-2024.

Termination of ATM Prospectus

On November 6, 2023, the Company delivered written notice to Jefferies LLC ("Jefferies") that it was suspending and terminating the prospectus related to the Company's common stock, $0.00001 par value per share (the "ATM Prospectus"), issuable pursuant to the terms of the Open Market Sale Agreement℠, dated November 1, 2022 (the "Sales Agreement"), by and between the Company and Jefferies. The Company will not make any sales of its securities pursuant to the Sales Agreement, unless and until a new prospectus, prospectus supplement or a new registration statement is filed. Other than the termination of the ATM Prospectus, the Sales Agreement remains in full force and effect.

A copy of the Sales Agreement was filed as Exhibit 1.2 to the Company's Registration Statement on Form S-3 filed with the U.S. Securities and Exchange Commission (the "SEC") on November 1, 2022.

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. 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. 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 forward looking statements include express or implied statements regarding Aura's future expectations, plans and prospects, including, without limitation, statements regarding, but are not limited to, the therapeutic potential of bel-sar for the treatment of cancers including CM, MIBC, NMIBC and choroidal metastasis; 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 CM and the Phase 1 trial of bel-sar for MIBC and NMIBC; the potential approvability of bel-sar; and the Phase 2 trial of bel-sar for CM.

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 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, 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; the risk that governmental authorities may disagree with the Company's clinical trial designs, even where the Company has obtained agreement with governmental authorities on the design of such trials, such as the Phase 3 SPA agreement with FDA; 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; the Company's ongoing and planned preclinical 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 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 No.	Description
99.1	Press Release dated November 6, 2023, titled "Aura Biosciences Receives FDA Agreement Under Special Protocol Assessment (SPA) for CoMpass Phase 3 Clinical Trial of Belzupacap Sarotalocan (Bel-sar) in Early-stage Choroidal Melanoma"
99.2	Corporate presentation of the Company
104	Cover Page Interactive Data File (embedded within 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 thereunto duly authorized.

Aura Biosciences, Inc.

Date: November 6, 2023

By: /s/ Julie Feder

Julie Feder
Chief Financial Officer

Aura Biosciences Receives FDA Agreement Under Special Protocol Assessment (SPA) for CoMpass Phase 3 Clinical Trial of Belzupacap Sarotalocan (Bel-sar) in Early-stage Choroidal Melanoma

Positive Clinical Efficacy Updates of Bel-sar for Early-Stage Choroidal Melanoma from the Ongoing Phase 2 Clinical Trial with Suprachoroidal Administration Presented at AAO 2023

Preliminary Data from Phase 1 Trial in Bladder Cancer – First Patient Utilizing a Single Dose of Bel-sar with Light Activation Demonstrated a Clinical Complete Response

BOSTON, MA – November 6, 2023 – Aura Biosciences, Inc. (NASDAQ: AURA), a clinical-stage biotechnology company developing a novel class of virus-like drug conjugate (VDC) therapies for multiple oncology indications, today announced it has received agreement from the U.S. Food and Drug Administration (FDA) under an SPA for the design and planned analysis of CoMpass, the Company's global Phase 3 clinical trial of bel-sar for the first-line treatment of adult patients with early-stage Choroidal Melanoma (CM). The Company also announced the presentation of positive Phase 2 safety and efficacy data of bel-sar with 90% of patients at twelve months of follow-up evaluating two key clinical endpoints: tumor control and visual acuity preservation using suprachoroidal (SC) route of administration for the first-line treatment of adult patients with early-stage CM. The results were presented at the American Academy of Ophthalmology (AAO) 2023 Annual Meeting, in San Francisco, California.

"This written agreement from the FDA is consistent with our regulatory strategy and reaffirms that the design and planned analysis of the CoMpass Phase 3 Clinical Trial, if successful, adequately address the objectives necessary to support a biologics license application submission for bel-sar for the treatment of early-stage CM," said Dr. Jill Hopkins, Chief Medical Officer and President of R&D of Aura Biosciences. "We are excited with the momentum in the ocular oncology community to participate in what would be the first ever registration-enabling clinical trial for early-stage CM."

"The Phase 2 data presented today, with 90% of patients at twelve months follow-up, show results that are highly consistent with and strongly support the assumptions for the design of the CoMpass trial. We have observed 80% tumor control and 90% visual acuity preservation for patients that have been treated with the therapeutic regimen of bel-sar and meet the Phase 3 enrollment criteria. The safety profile continues to be favorable with no treatment-related Serious Adverse Events or significant Adverse Events. This is very encouraging as most 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. Carol Shields, Chief of the Ocular Oncology Service at Wills Eye Hospital and Professor of Ophthalmology at Thomas Jefferson University (USA). "We are excited for the possibility to have for the first time a vision preserving therapy, expanding the possibility to treat patients earlier than we do today."

The presentation can be accessed on the Company's website here.

Agreement from the FDA Under an SPA for the Global Phase 3 CoMpass Trial:

The Company received written agreement from the FDA under an SPA for the design and planned analysis of the Global Phase 3 CoMpass trial indicating concurrence by the FDA with the adequacy of the study, if successful, to address the objectives necessary to support the Company's planned biologics license application submission. The Phase 3 trial is designed as a superiority trial comparing bel-sar versus sham. The trial is a global, multi-center, masked study, and it is intended to enroll approximately 100 patients randomized 2:1:2 to receive high dose regimen of bel-sar with SC administration, low dose regimen of bel-sar with SC administration, or a sham control. The primary endpoint is time to tumor progression, and the first key secondary endpoint is a composite time to event analysis that will compare the tumor control and visual acuity of the bel-sar high dose regimen to sham when the last patient completes their 15 months of follow up. The trial is powered at greater than 90%. The Company is on track to dose the first patient in Q4 2023.

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

The 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 CM. A total of 22 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=16). Cohorts 5 and 6 (n=13) 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=10) 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 in the analysis. All patients in Cohorts 5 and 6 had active tumor 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 control, visual acuity preservation and tumor growth rate as the defined clinical endpoints to evaluate preliminary efficacy. The results, with 90% of patients at twelve months of follow-up who received three cycles of therapy in Cohorts 5 and 6, and who match the criteria for the global Phase 3 trial, showed a tumor control rate of 80% (8/10) and the visual acuity preservation rate was 90% (9/10). The majority of patients being at high-risk for vision loss with tumors close to the fovea or optic disk. For the 80% of patients that responded, data showed a statistically significant reduction in tumor growth rate (-0.382 mm/yr, $p = <0.0001$) compared to each patient's documented growth rate at study entry. The overall tolerability profile of bel-sar was favorable, with no dose-limiting toxicities, treatment-related SAEs or significant AEs reported as of August 3, 2023. There was no posterior inflammation and only mild anterior inflammation (Grade 1) in ~18% of the patients which was self-limited or resolved with a short course of topical steroids. Treatment-related AEs were predominantly mild and resolved without sequalae. We believe these updated 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 at an early stage and have no approved therapies to date.

Preliminary Data from Phase 1 Trial in Bladder Cancer

The trial has completed enrollment of the cohort that received bel-sar injection without light activation. Protocol mandated safety review found no safety issues and the study has proceeded to the bel-sar injection plus light activation cohorts. Preliminary data from the first patient in the light activated cohort of the trial, utilizing a single dose of bel-sar with light activation, demonstrated a clinical complete response demonstrated by absence of cancer cells on histopathology with evidence of extensive necrosis and immune activation.

Bel-sar is a novel investigational agent designed with a dual mechanism of action that includes targeted cytotoxicity and immune activation. The ongoing Phase 1 multi-center, open-label clinical trial is expected to enroll approximately 19 adult patients. The trial is designed to assess the safety and tolerability of bel-sar as a single agent. The trial will provide histopathological evaluation after the local treatment to assess bel-sar's biological activity. In addition, the FDA has allowed an amendment to the protocol of the Company's ongoing Phase 1 trial evaluating bel-sar, allowing the inclusion of adult patients with muscle invasive bladder cancer in addition to non-muscle invasive bladder cancer. The Company expects to provide more data mid-2024.

About Aura Biosciences

Aura Biosciences, Inc. is a clinical-stage biotechnology company developing 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 the standard of care with radiotherapy leaves patients with severe comorbidities, including significant 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 and muscle invasive bladder cancer. Aura is headquartered in Boston, MA.

For more information, visit aurabiosciences.com, or follow us on Twitter and LinkedIn

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, muscle invasive bladder cancer, non-muscle invasive bladder cancer and choroidal metastasis; 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 the Phase 1 trial of bel-sar for muscle invasive bladder cancer and non-muscle invasive bladder cancer; and the potential approvability of bel-sar; the Phase 2 trial of bel-sar for choroidal metastasis.

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, 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; the risk that governmental authorities may disagree with Aura's clinical trial designs, even where Aura has obtained agreement with governmental authorities on the design of such trials, such as the Phase 3 SPA agreement with FDA; 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; Aura's ongoing and planned preclinical 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

Exhibit 99.2

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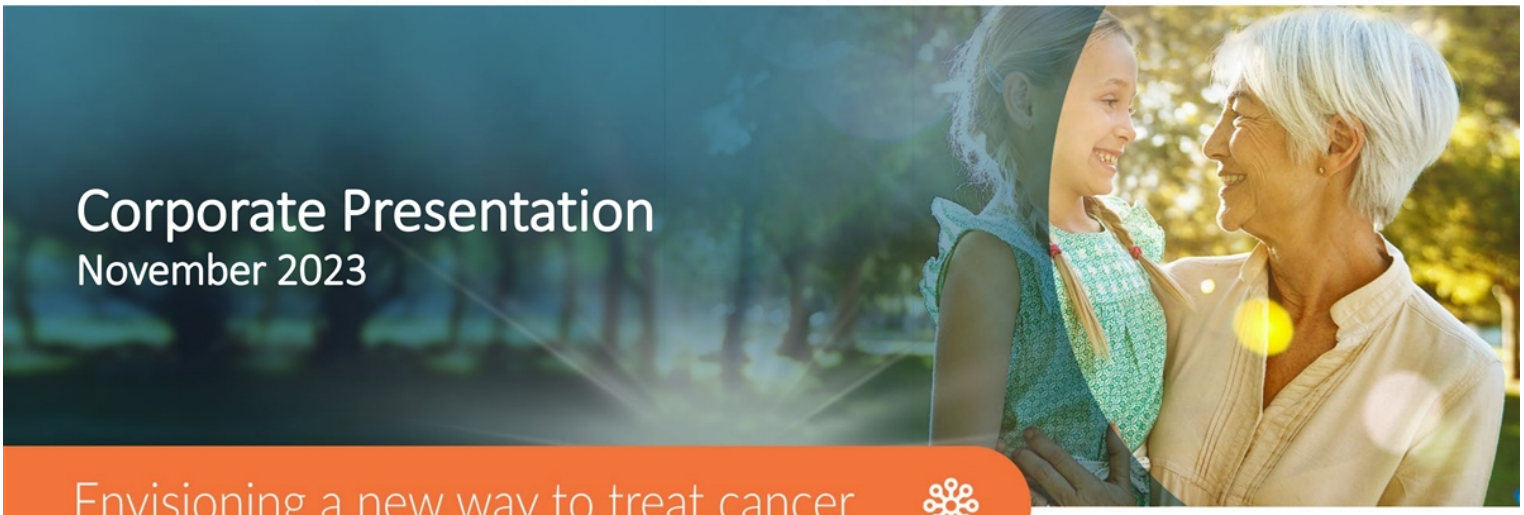

Corporate Presentation

November 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; 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 and Quarterly Report on Form 10-Q 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

Virus-Like Drug Conjugates (VDCs)

- Novel class of drugs to treat solid tumors
- Dual Mechanism of Action: targeted cytotoxicity and immune activation

Ocular Oncology Franchise

- Special Protocol Assessment (SPA) Agreement with FDA:
  - *Global Ph 3 study design and analysis supports regulatory submission in Primary Choroidal Melanoma*
- Ph 2 data supports assumptions for Ph 3 study (powered at 95%)
- Global Ph 3 ongoing with many sites activated in the US

Urologic Oncology Franchise

- We believe preliminary data supports dual MoA with complete response and immune activation after single dose confirmed by histopathology
- Updated protocol includes both NMIBC and MIBC

Strong Cash Position

- Current cash runway expected to fund operations into 2H 2025

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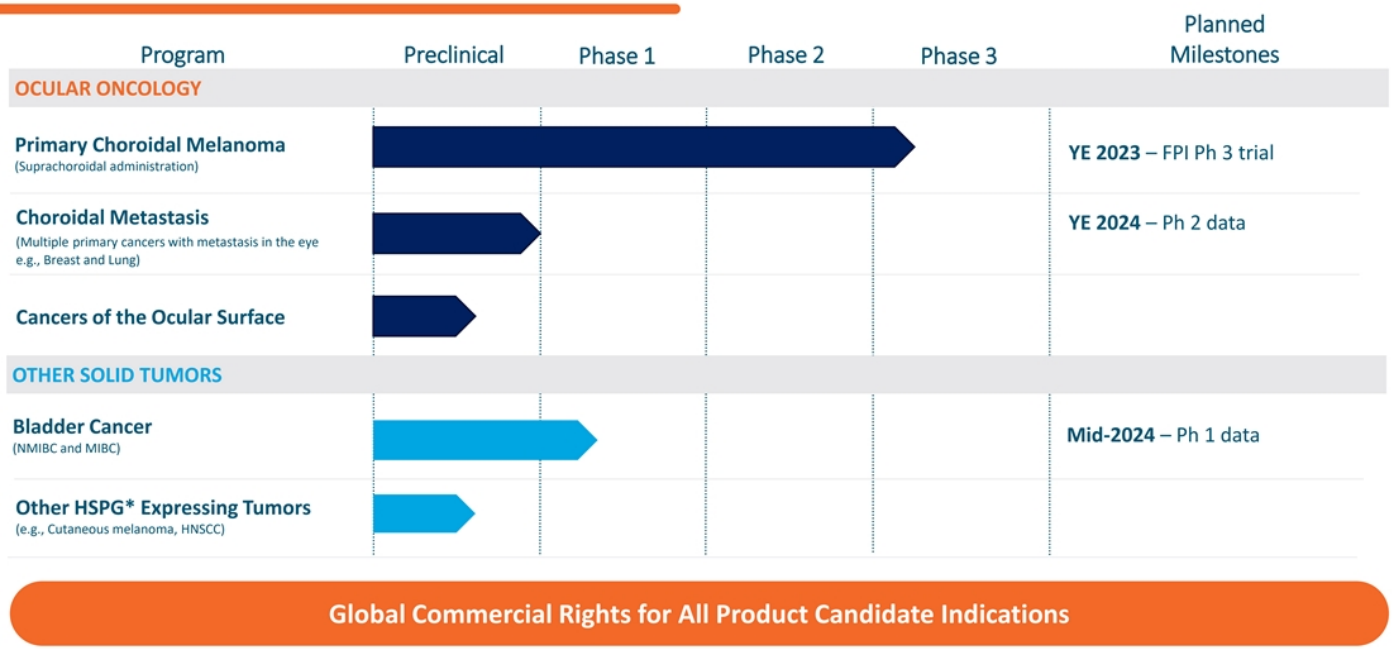
Pipeline Targeting Life-Threatening Cancers with High Unmet Needs



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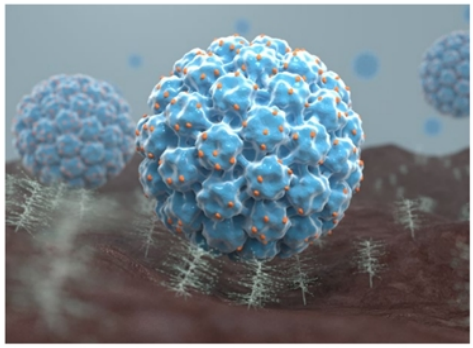
Targeted Oncology Platform: Virus-Like Drug Conjugates (VDCs)

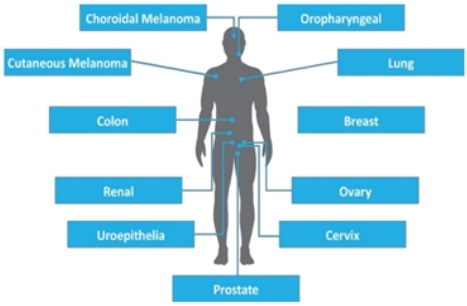
Virus-Like Particle Conjugated to a Cytotoxic Payload

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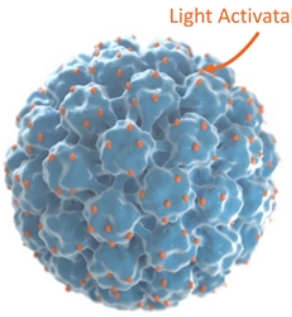
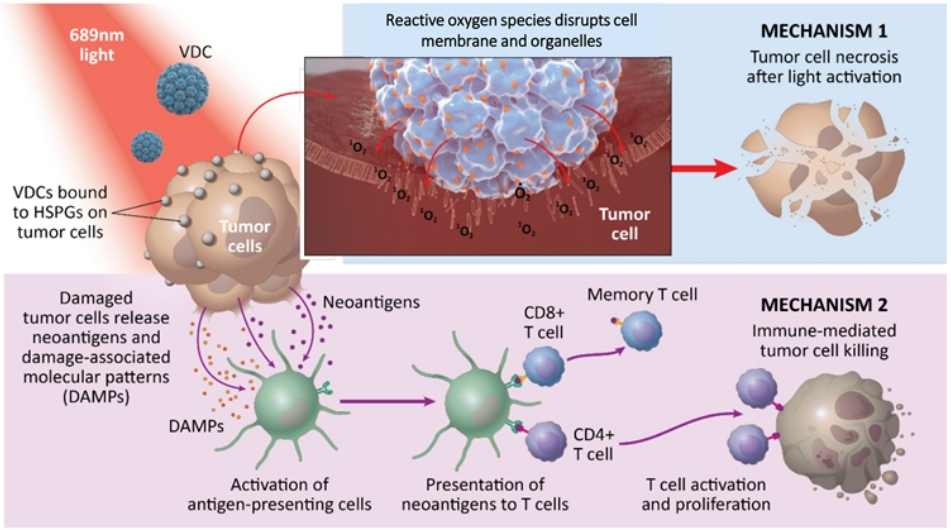
Bel-sar is a VDC with a Novel Dual Mechanism of Action



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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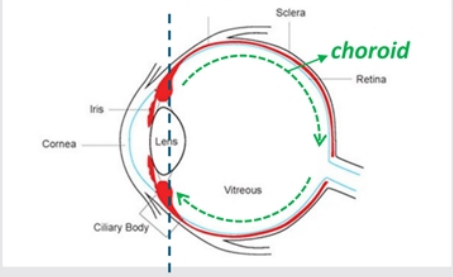
Primary Choroidal Melanoma—High Unmet Medical Need

Choroid is 90%
of the uvea[1]

50% of patients develop metastasis within 15 years (metastatic uveal melanoma)[2]

Uvea: Choroid, Ciliary Body and Iris



Most common primary intraocular cancer in adults[2]

Impacts **~11,000** patients in US/Europe per year[3]

~80% patients diagnosed with **early-stage disease**[3]

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

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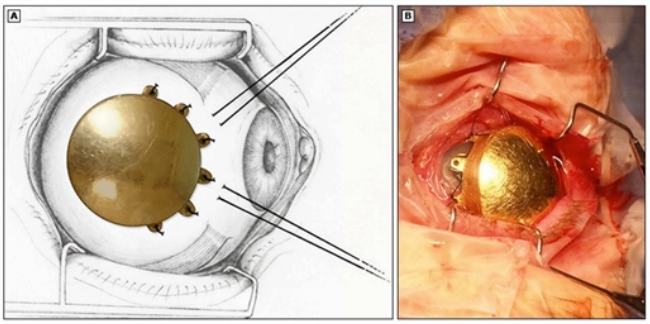
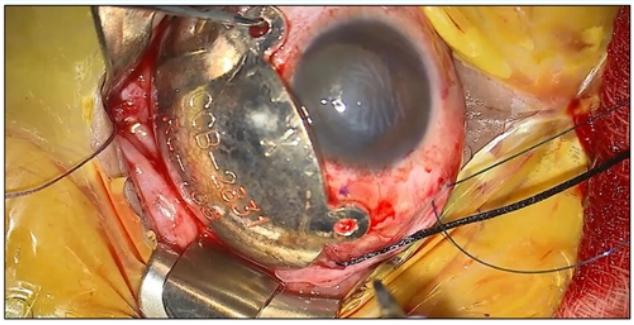
Radiotherapy is the Standard of Care for Early-Stage Disease

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[1]
(B) Intraoperative photograph showing COMS plaque in place. The plaque stays in place for 3 to 7 days[1]



Surgical treatment of large choroidal melanoma with ruthenium 106 plaque brachytherapy[2]

Maculopathy, Cataract, Glaucoma, Vitreous Detachment and Vitreous Hemorrhage are Common Vision Threatening Complications of Brachytherapy[3]

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.2019.87407

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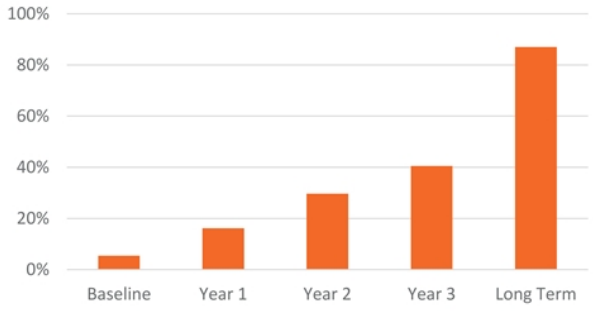
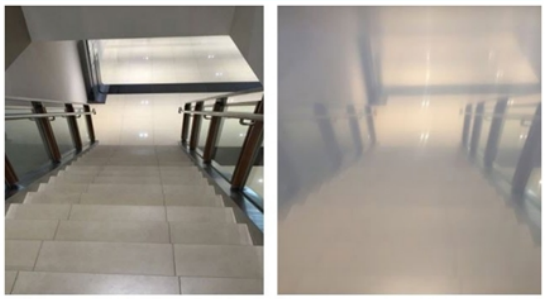
Up to 87% of Patients Will be Blinded when Treated with Radiotherapy

Proportion of Patients Legally Blind (BCVA ≤20/200) after Brachytherapy[1,2]



Contrast Sensitivity Diminishes Significantly within the First Year after Brachytherapy and Continues to Deteriorate Over Time[2]



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.

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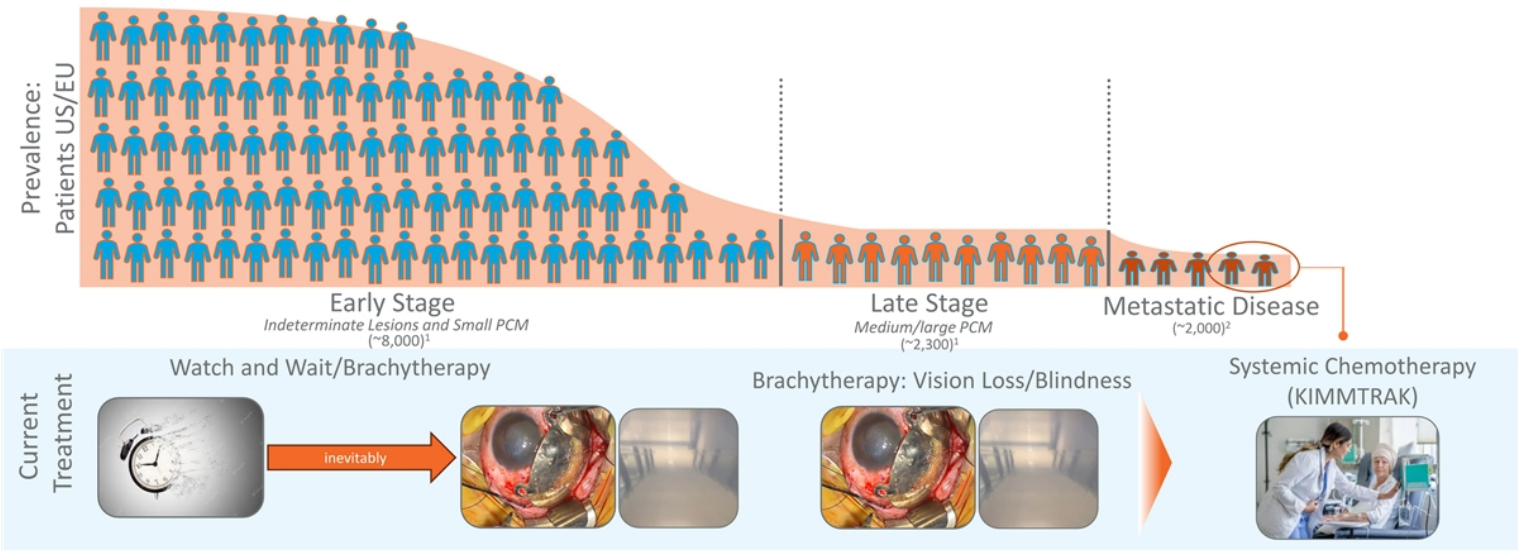
Benefit/Risk of Radiotherapy Drives "Watch and Wait" in Patients with Early-Stage Disease



Most of the Addressable Population is Untreated Due to Risk of Treatment Related Vision Loss and Severe Comorbidities

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

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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 Suprachoroidal Injection

Two injections (2min. each) 30 min apart

3-4h

Light Activation with Standard Ophthalmic Laser

10-30 min. procedure

In-Office

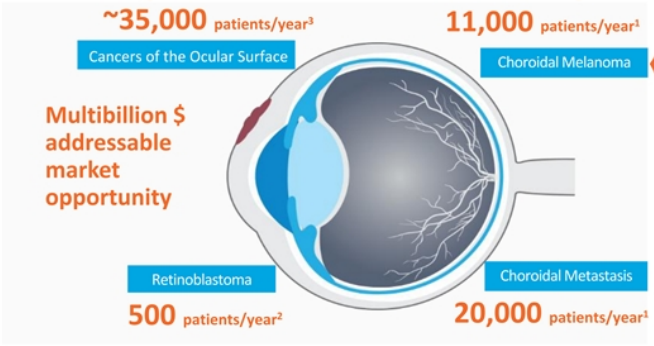
Goals of Treatment

- Local tumor control
- Preservation of vision
- No radiation-related morbidity
- 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

~66,000 patients/year

Ocular Oncology Franchise total addressable market (US/EU)



11,000 patients/year

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 ~87% of patients with major irreversible vision loss

~100

Ocular Oncologists in US/EU — focused call point

<20

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

1. ClearView & Putnam & Assoc. Epidemiology Analysis Choroidal Melanoma and Choroidal Metastasis
2. American Cancer Society- Retinoblastoma statistics
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/)

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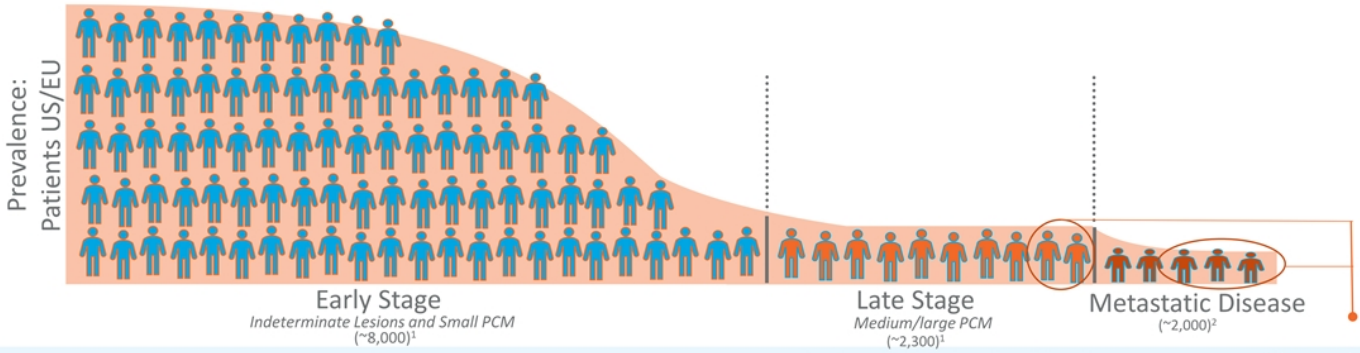
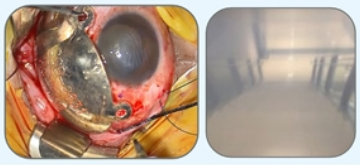
Potential Future Patient Treatment Journey



Treatment

First Line Treatment with Bel-sar

Brachytherapy: Vision Loss/Blindness



Chemotherapy (KIMMTRAK)

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

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

Adverse Event or Adverse Reactions	KIMMTRAK[1] Any Grade	Darovasertib + Crizotinib Combination[2] Any Grade	Bel-Sar 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

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Choroidal Melanoma Ph 2 Data

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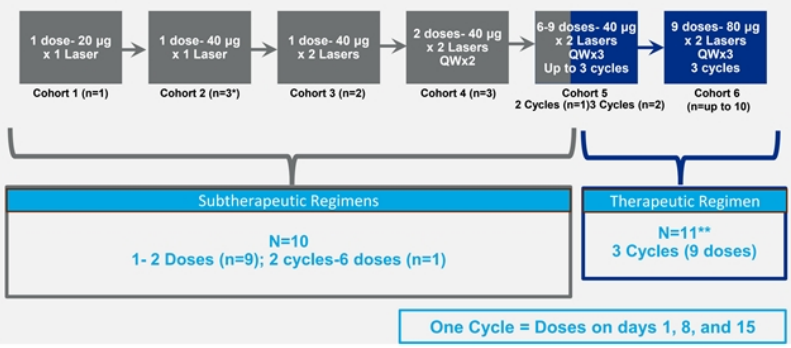
Ph 2 Trial – Dose Escalation and Expansion with Suprachoroidal Administration

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

Endpoint	Endpoint Definitions
Tumor Progression	Growth in Tumor Height ≥0.5mm or ≥1.5 mm in Largest Basal Diameter (LBD)
Visual Acuity Loss	Decrease from Baseline: ≥15 letters
Tumor Thickness Growth Rate	Change in Rate of Growth of Tumor Thickness

Trial Design – Enrollment Complete (n=22)



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

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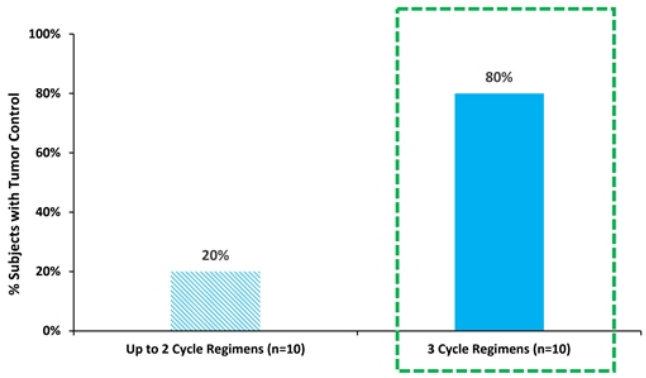
High Tumor Control Rates Observed – Durable at 12 Months Follow Up

Dose Response: Subtherapeutic vs Therapeutic Regimen



>90% Completed 12 Months

Dose/Regimen	Total Patients (n)	Tumor Control 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)

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

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

High Tumor Control Rates with Therapeutic Regimen in Ph 3 Eligible Patients with Active Growth

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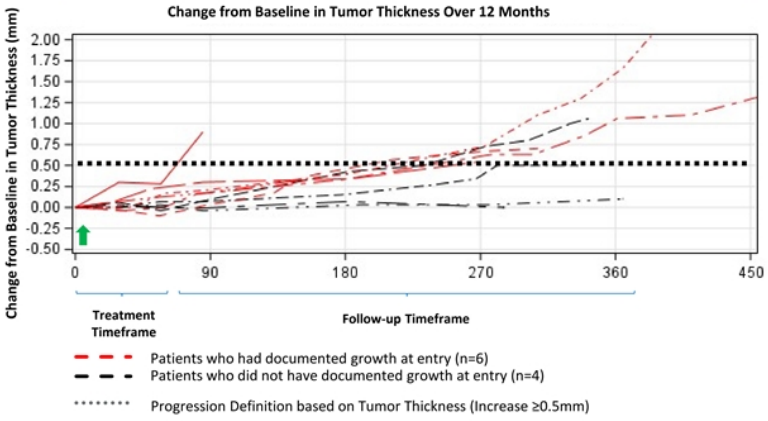
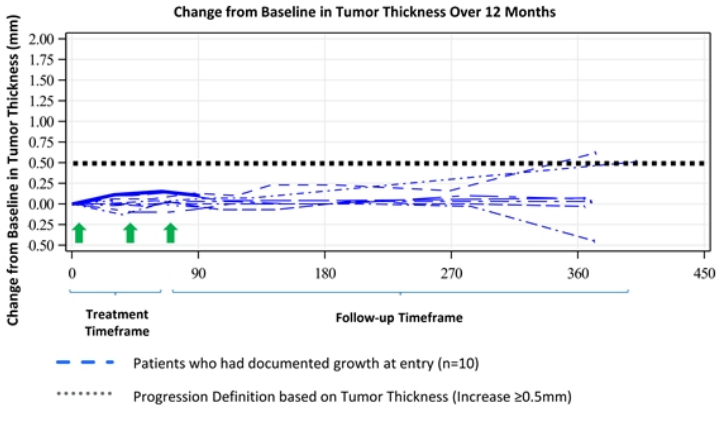
High Tumor Control Rates Observed in Ph 3 Population Treated with Therapeutic Regimen

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

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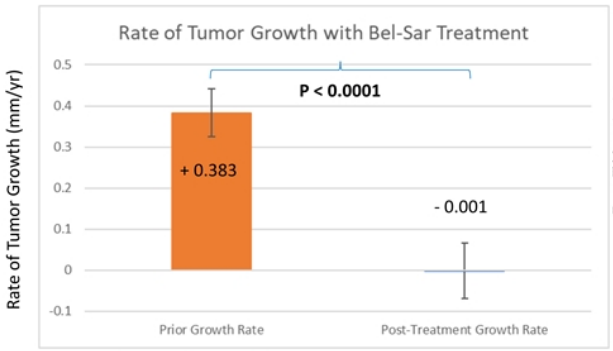
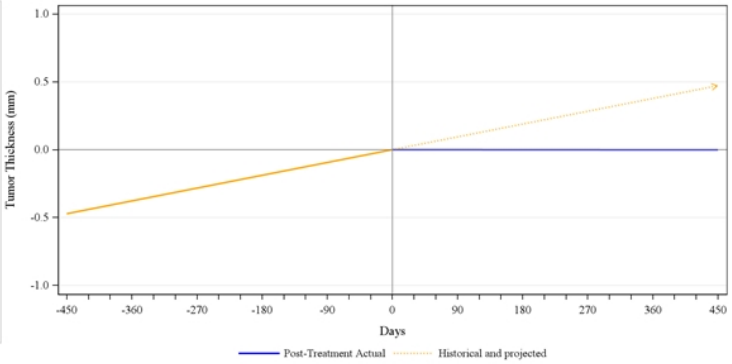
Ph 2 Interim Data Demonstrated a Negative Growth Rate Post-Treatment

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)

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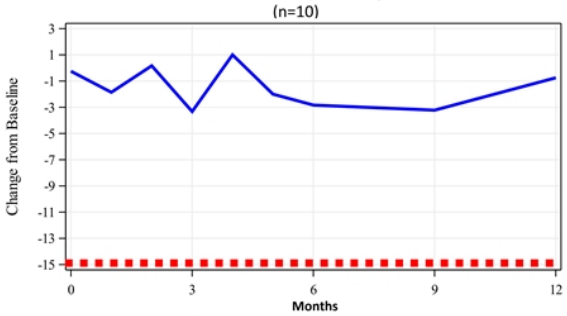
90% Visual Acuity Preservation Despite 80% of These Patients Being at High Risk for Vision Loss

>90% Patients Completed 12 months

Median Change in BCVA in Ph3 Eligible Patients with Therapeutic Regimen (n=10)



Vision acuity loss definition based on ETDRS BCVA letter score (≥ 15 letters from baseline)

Vision Loss (15 letters)

August 3, 2023, data on file Aura Biosciences

Populations	Total Patients (n)	Vision Failures (n)	Vision Preservation Rate
All Dose Cohorts			
All Treated Patients	22	1	96%
Subtherapeutic			
Single dose up to 2 cycles	10	0	100%
Therapeutic Regimens			
3 Cycles (n=11)	11	1	91%
3 Cycles and Ph 3 eligible (n=10)*	10	1	90%

*One subject with circumpapillary tumor that doesn't meet Ph 3 criteria is not included

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

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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) Drug/Laser Related Adverse Events >5% Subjects*	**Grade I**	**Grade II**	**Grade III**	**Total**
Anterior Chamber 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%++

* 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.
+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

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Randomized Controlled Global Ph 3 Trial

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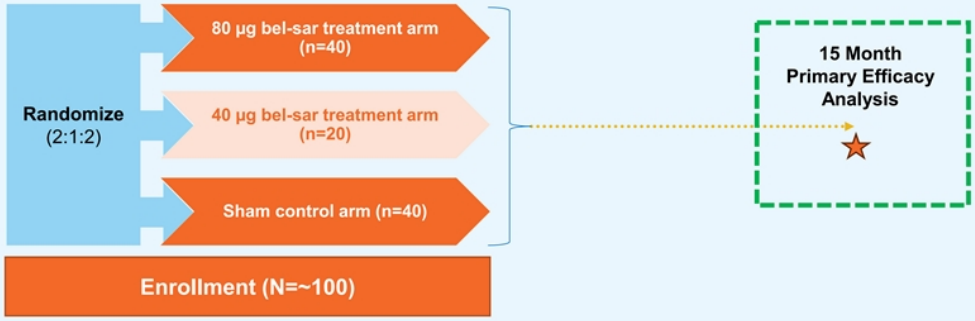
SPA Agreement with FDA Supports Global Ph 3 Trial Design

Fast Track and Orphan Designations



SPA Agreement

Primary Endpoint

- Time to Tumor Progression

First Key Secondary Endpoint

- Time to Composite Endpoint: Tumor Progression or Visual Acuity Failure

An SPA Indicates Concurrence by the FDA that the Design of the Trial can Adequately Support a Regulatory Submission

SPA – Special Protocol Assessment; Bel-sar – Belzupacap Sarotalocan

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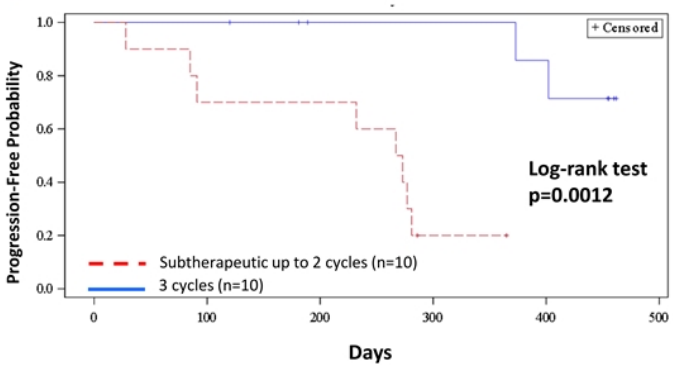
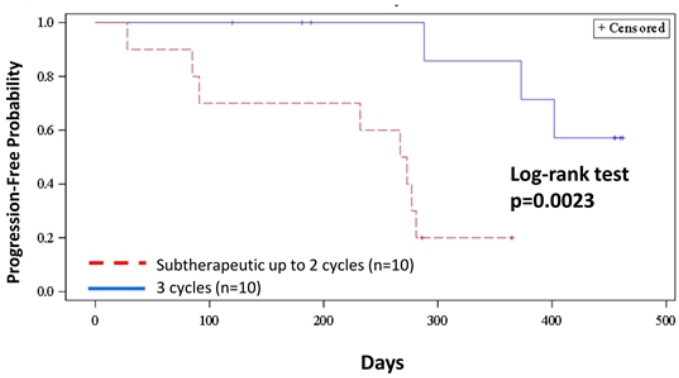
Kaplan-Meier Analysis Simulation of Key Primary & Secondary Endpoint with Ph 2 Data

Time to Tumor Progression



Time to Composite Endpoint



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

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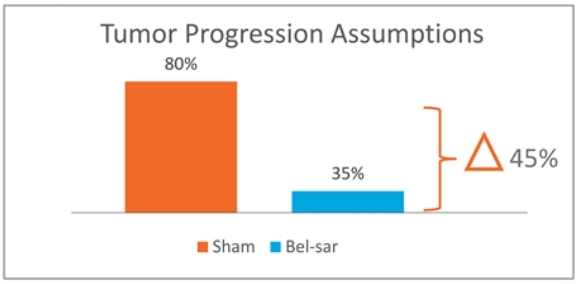
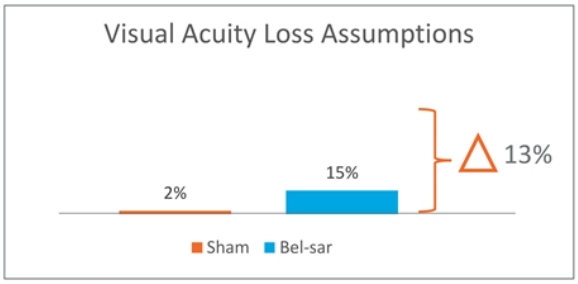
Clinical Endpoints to Support Potential Approval in Alignment with Regulatory Agencies

	Endpoint	Endpoint Assumptions	Endpoint Definitions
Composite Endpoint	**Tumor Progression**	**Bel-sar:** 35% Tumor Progression **Sham:** 80% Tumor Progression	Growth in Tumor Height ≥0.5mm or ≥1.5 mm in Largest Basal Diameter
	Vision Acuity Loss	**Bel-sar:** 15% VA Loss **Sham:** 2% VA Loss	Decrease from baseline: ≥15 letters





Conservative Assumptions Provide Support for Potential for Regulatory Submission (Phase 3 Trial Powered at 95%)

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

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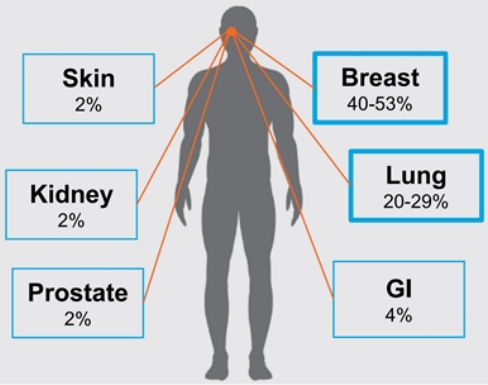
Choroidal Metastasis

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 Daily Radiotherapy for 4 Weeks

Vision Loss and Radiation Associated Complications

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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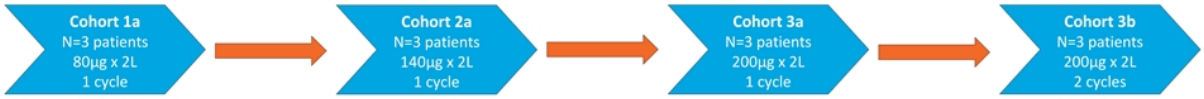
Choroidal Metastasis – Ph 2 Trial Design

Study Design (n=12*)



Study Objectives

- Safety/DLT
- Efficacy
  - Choroidal Tumor Progression
  - Choroidal Tumor Growth rate
  - Vision improvement

Study Population

- Patients with unilateral, unifocal choroidal metastasis
- Breast or Lung Primary
- No changes in concurrent systemic medications planned

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

*3+3 Design. Each cohort will have a minimum of 3 and a maximum of 6 patients.

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Urologic Oncology

Bel-sar
INN: belzupacap sarotalocan

Target Indications:

Bladder Cancer

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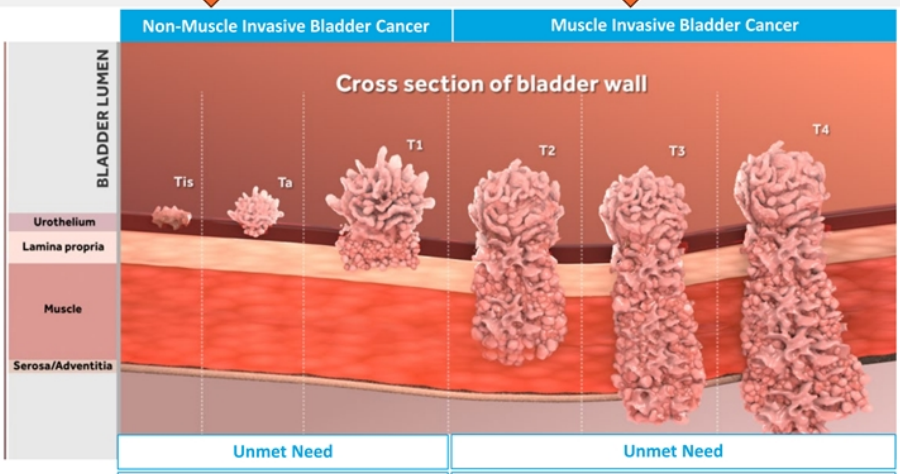
Bladder Cancer is a High Unmet Medical Need

~500,000
New cases/ year globally[1]

61,000
New cases/year in the US[1]

20,000
New cases/year in the US[2]



Unmet Need	Unmet Need
Recurrence, multiple TURBT surgeries, Progression of Disease, Loss of Bladder/Cystectomy	Progression of Disease, Loss of Bladder/Cystectomy, Metastasis and Survival

1. Putnam & Assoc. Epidemiology Analysis
2. Campbell-Walsh-wein Urology, 2021, 12th edition ; Chapter 137, page 3112

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

Illustrative **Current** Bladder Cancer Patient Journey

Presents with Blood in urine → Urologist → Diagnosis and Treatment Plan → TURBT → BCG >6 tx → BCG Refractory ⇄ Intravesical gene therapy (Adstiladrin) → Cystectomy

Adjuvant Therapy → BCG >6 tx

recurrence → INTRAVESICAL CHEMOTHERAPY

BCG Refractory ⇄ Systemic Immunotherapy (Keytruda)

Illustrative **Future** Bladder Cancer Patient Journey

Presents with Blood in urine → Urologist → Diagnosis and Treatment Plan → **Bel-sar + TURBT**

Adding Bel-sar can potentially:

- *Prevent Recurrence after TURBT*
- *Avoid need for Adjuvant Chemotherapy*
- *Avoid need for six cycles of BCG*
- *Increase efficacy of checkpoint inhibitors*
- *Prevent Cystectomy*

BCG – Bacillus Calmette Guerin;
TURBT- transurethral resection of bladder tumor

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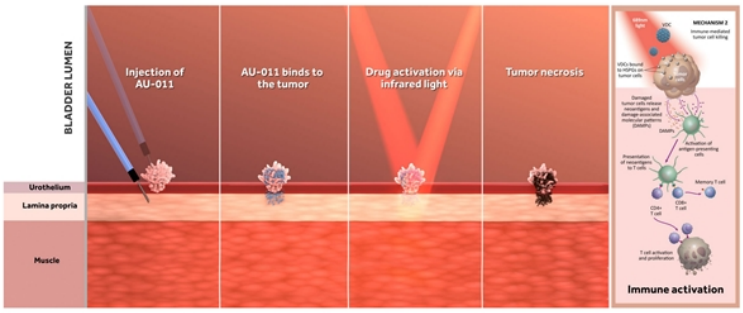
Bel-Sar has a Unique MoA Designed for the Local Treatment

Local Administration and Light Activation with Standard Cystoscope



Treatment Aligned with Current Urologic Oncology Practice

Lasers are commonly used by urologists

Bladder injections are common and simple to perform (e.g., Botox)

Local delivery in the bladder increases tumor drug exposure

Precedent for immune-mediated tumor clearance (BCG & checkpoint inhibitors)

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

Bel-sar, AU-011 – Belzupacap Sarotalocan
MoA – Mechanism of Action

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Ph 1 Trial Designed to Evaluate Safety, Feasibility and MoA

Study Design and Objectives (n=19)

Part 1 (n=5)
Bel-sar Alone

→ **Completed**

No treatment-related adverse events, serious adverse events or dose-limiting toxicities were seen for the 5 patients

Part 2 (n=14)
Bel-sar + Focal Light Activation

→ **Ongoing**

Study Objectives

- Safety/DLT
- Feasibility of technique
- Focal distribution of bel-sar
- Focal necrosis
- Markers of immune activation

Study Population

- TURBT and cystectomy patients
- NMIBC and MIBC patients

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

Bel-sar – Belzupacap Sarotalocan
MoA – Mechanism of Action
TURBT- transurethral resection of bladder tumor

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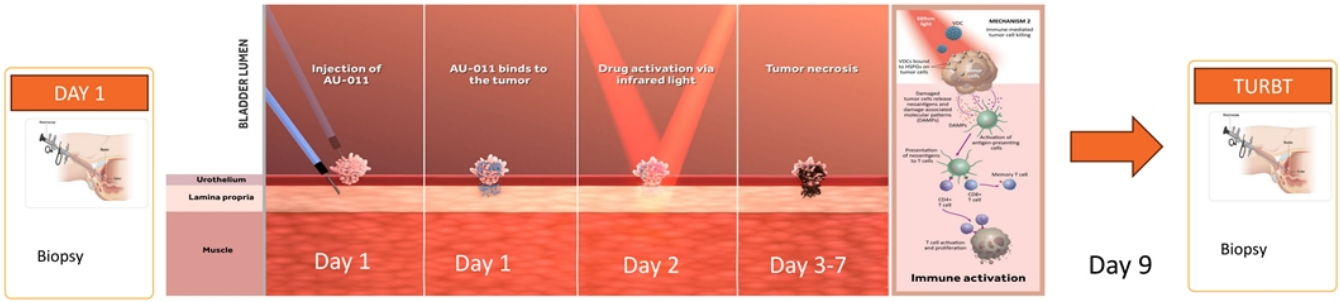
Clinical Complete Response with Immune Activation after Single Dose Confirmed by Histopathology

Ph 1- Preliminary Data Light Activated Cohort (n=1)



Day 1
Diagnostic biopsy shows non-invasive, 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^2)
(~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)

Bel-sar, AU-011 – Belzupacap Sarotalocan
TURBT- transurethral resection of bladder tumor

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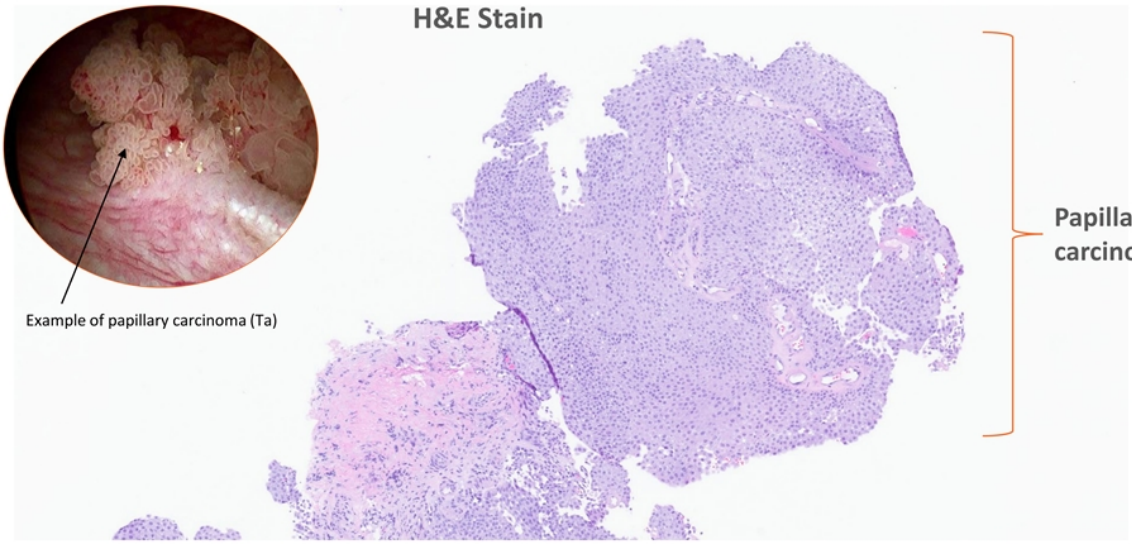
Pre-Treatment Biopsy (Day 1) shows Papillary Urothelial Carcinoma



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

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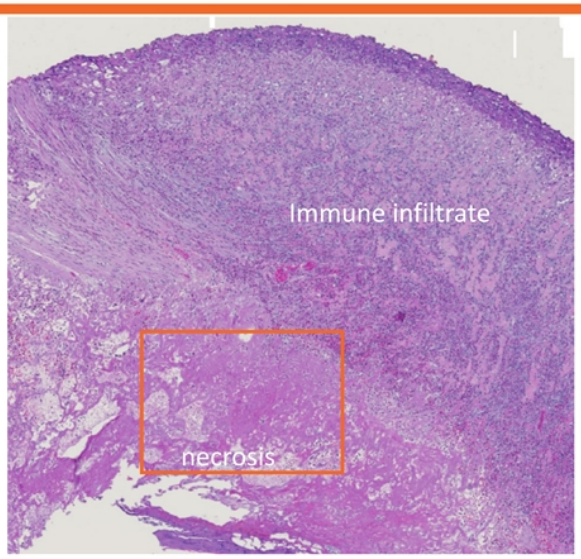
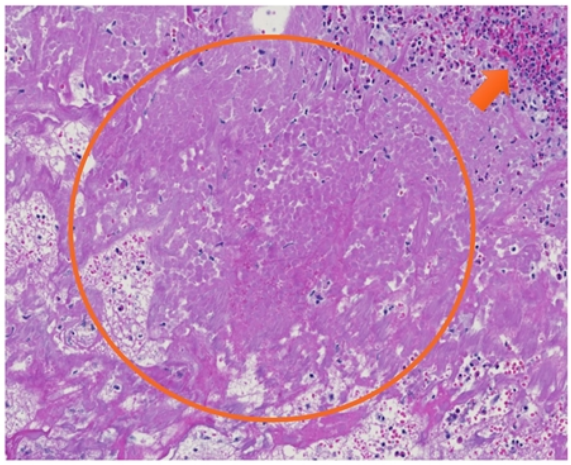
Clinical Complete Response Confirmed by Histopathology after Single Dose of Bel-sar

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

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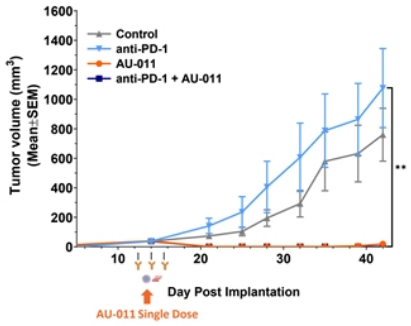
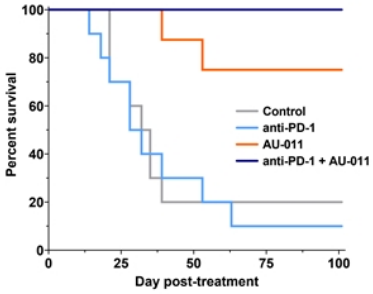
Durable CRs with Single Administration of Bel-sar in Bladder Cancer Model

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

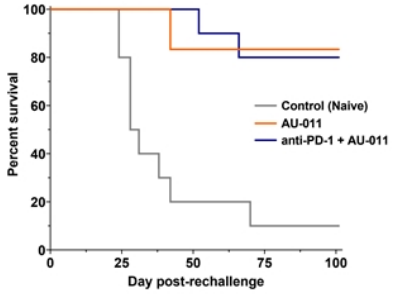
Tumor Regression



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 Demonstrated 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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Strategy & Key Milestones

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Aura Biosciences Investment Highlights

Key Highlights

- **Primary Choroidal Melanoma**
  - **SPA Agreement** with FDA supports regulatory submission
  - **Ph 2 data supports assumptions** for Ph 3 study (powered at 95%)
  - **Global Ph 3 trial ongoing** with many sites activated in the US
- **Bladder Cancer (NMIBC/MIBC)**
  - We believe preliminary data supports dual MoA with **clinical complete response and immune activation confirmed by histopathology**

Expected Clinical Milestones within 6-12 months

Primary Choroidal Melanoma:
- YE 2023: Dose first patient in global Ph 3 trial

Choroidal Metastasis:
- YE 2024: Ph 2 data

Bladder Cancer (NMIBC/MIBC):
- Mid-2024: Ph 1 data

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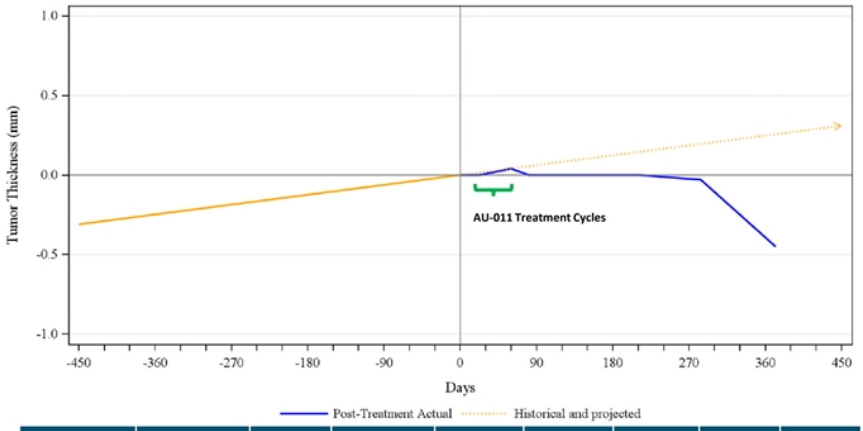
Bel-Sar Has Shown Long Term Durable Response with Visual Acuity Preservation in Phase 3 Eligible Patient



	Baseline	Wk 4	Wk 6	Wk 12	Wk 16	Wk 30	Wk 39	Wk 52
BCVA	79	87	84	85	85	80	85	85

Base Line Characteristics	
Phase 3 Eligible Subject	
Documented Tumor Growth	Yes
Tumor Size at Baseline	
Tumor Height	1.03 mm
Largest Basal Diameter (LBD)	6.12 mm
Risk Factors	
Subretinal Fluid (F)	Yes
Orange Pigment (O)	Yes
Decreased Vision Caused by Tumor	Yes
Location	
Distance to Fovea	0 mm
Distance to Optic Nerve	0 mm (4 clock hrs.)

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