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): September 12, 2024

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.

On September 12, 2024, Aura Biosciences, Inc. (the "Company") announced positive Phase 2 end of study results evaluating bel-sar (AU-011) for the first-line treatment of early-stage choroidal melanoma (CM). The results were presented at The Retina Society Annual Meeting, on Thursday, September 12, 2024, in Lisbon, Portugal. The Company issued a press release announcing these and other updates titled "Aura Biosciences Reports Positive Phase 2 End of Study Results Evaluating Bel-sar as a First-Line Treatment for Early-Stage Choroidal Melanoma". 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 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.

On September 12, 2024, 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 the Company's research and development programs and the Company's 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 the Company's research and development programs; statements regarding the Company's expectations for an improved quality of life of patients after treatment with bel-sar; the Company's ability to successfully manufacture its 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 the Company's third-party strategic collaborators to continue research and development activities relating to the Company's development candidates and product candidates; the Company's ability to commercialize its products, if approved; the Company's ability to obtain funding for its operations necessary to complete further development and commercialization of its product candidates; the Company's ability to obtain and maintain regulatory approval of its product candidates; the size and growth potential of the markets for the Company's product candidates, and the Company's ability to serve those markets; the Company's financial performance; the Company's expected cash runway into the second half of 2026; and the implementation of the Company's business model, including strategic plans for its 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, 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 preclinical and 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 Special Protocol agreement with the United States Food and Drug Administration; 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 United States 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 under this Item 8.01 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 September 12, 2024.
99.2	Corporate Presentation of the Company.
104	Cover Page Interactive Data File (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.

Aura Biosciences, Inc.

Date: September 12, 2024

By: /s/ Julie Feder

Julie Feder
Chief Financial Officer

Exhibit 99.1

Aura Biosciences Reports Positive Phase 2 End of Study Results Evaluating Bel-sar as a First-Line Treatment for Early-Stage Choroidal Melanoma

Bel-sar Demonstrated 80% Tumor Control Rate, 90% Visual Acuity Preservation, and a Highly Favorable Safety Profile

Aura to Host a Virtual Ocular Oncology Investor Event Featuring Key Opinion Leaders Today at 8:00 am ET

BOSTON, MA – September 12, 2024 – Aura Biosciences, Inc. (NASDAQ: AURA), a clinical-stage biotechnology company developing precision therapies for solid tumors designed to preserve organ function, today announced positive Phase 2 end of study results evaluating bel-sar (AU-011) for the first-line treatment of early-stage choroidal melanoma (CM), a vision and life-threatening ocular cancer. The results were presented at The Retina Society Annual Meeting, on Thursday, September 12, 2024, in Lisbon, Portugal.

The Phase 2 study (NCT04417530) is an open-label, ascending single and repeat dose escalation trial in patients with early-stage CM (small CM and indeterminate lesions) designed to evaluate the safety, tolerability, and efficacy of up to three cycles of bel-sar treatment. The trial included both single and multiple ascending dose cohorts, with a total of 22 patients enrolled. Patients were closely monitored over a twelve-month follow-up period to assess tumor control, visual acuity preservation, and tumor growth rate.

Tumor Control and Visual Acuity Preservation

The Phase 2 results demonstrated that bel-sar achieved an 80% tumor control rate (n=8/10) among Phase 3-eligible patients who received the therapeutic regimen, with complete cessation of growth following treatment among responders (post-treatment average growth rate of 0.011 mm/yr among responders compared to 0.351 mm/yr prior to study entry; $p<0.0001$). Visual acuity preservation was achieved in 90% of these 10 patients. Importantly, 80% of these 10 patients were at high risk for vision loss with tumors close to the fovea or optic disc, highlighting the potential for vision preservation with this novel class of drugs. Of note, the current standard of care is radiotherapy, which leads to visual acuity of <20/200 (the cutoff for legal blindness) in the treated eye in up to 87% of patients.[1] The Phase 2 results are a significant achievement considering the typically poor prognosis associated with choroidal melanoma, a rare and life-threatening ocular cancer, where there are no approved vision-preserving therapies to date.

[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.

Highly Favorable Safety Profile with No Dose-Limiting Toxicities

The safety profile of bel-sar was highly favorable in all participants regardless of dose. There were no treatment-related serious adverse events (SAEs) reported. Ocular treatment-related AEs (TRAEs) were mild (Grade 1), included anterior chamber inflammation (18%) or cell (9%) and resolved without sequelae. The vast majority (~70%) of the anterior chamber inflammation/cell events were self-limited, requiring no treatment, and resolved in a median of 6 days. For those events that did require treatment, topical steroid eye drops, administered for a median of 6 days, achieved complete resolution of the inflammation. Eye pain occurred in 9% of patients and was mild (Grade 1). Importantly, no treatment-related posterior inflammation events (no vitritis, choroiditis, retinitis, retinal pigment epithelium changes, or vasculitis) were reported.

“Many patients with early-stage choroidal melanoma currently face the difficult choice of whether to treat the cancer and risk losing their vision in the treated eye, or delay treatment and risk the tumor progressing,” said Dr. Ivana Kim, Director of the Ocular Melanoma Center, Mass Eye and Ear / Harvard Medical School. “The Phase 2 end of study data that I presented at The Retina Society Annual Meeting showed 80% tumor control rate, 90% vision preservation, and a highly favorable safety profile in early-stage CM. Bel-sar has the potential to become the first treatment that achieves the dual goals of treating the tumor while also preserving vision, which could change the treatment paradigm for patients with this disease.”

“We believe these Phase 2 results provide clinical evidence for bel-sar as a potential vision-sparing, first-line treatment option for patients with early-stage CM,” said Dr. Jill Hopkins, Chief Medical Officer and President of Research and Development at Aura Biosciences. “Bel-sar is potentially a first-in-class novel therapy and we are excited to continue to advance this program, which is currently enrolling patients in our ongoing global Phase 3 CoMpass trial.”

Aura received written agreement from the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (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 Aura’s planned biologics license application submission. Aura Biosciences is focused on enhancing treatment options and improving outcomes for patients with CM and other cancers.

Aura Virtual Ocular Oncology Investor Event

Aura will host a virtual ocular oncology investor event featuring Dr. Ivana Kim, MD (Mass Eye and Ear) and Dr. Prithvi Mruthyunjaya, MD, MHS (Stanford University Byers Eye Institute) to discuss the Phase 2 end of study data on Thursday, September 12, 2024, at 8:00 am Eastern Time. To register for the event, click here. A live question and answer session will follow the formal discussion.

The live webcast of Aura’s virtual ocular oncology investor event will be available on the “Investors & Media” page under the “Events & Presentations” section of Aura’s website at https://ir.aurabiosciences.com/events-and-presentations, where a replay of the webcast will be archived for 90 days following the presentation date.

About Aura Biosciences

Aura Biosciences is a clinical-stage biotechnology company focused on developing precision therapies for solid tumors that aim to preserve organ function. Our lead candidate, bel-sar (AU-011), is currently in late-stage development for primary choroidal melanoma, and in early-stage development in other ocular oncology indications and bladder cancer. Aura Biosciences is headquartered in Boston, MA. Our mission is to grow as an innovative global oncology company that positively transforms the lives of patients.

For more information, visit aurabiosciences.com. Follow us on X (formerly Twitter) @AuraBiosciences and visit us on 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 early-stage CM and other oncology indications; statements regarding Aura's expectations for the Phase 3 clinical trial of bel-sar for early-stage CM; statements regarding Aura's expectations for an improved quality of life of patients after treatment with bel-sar; statements regarding Aura's beliefs and expectations for the urgent need for an effective local treatment in ocular and other oncology indications to preserve organ function; statements regarding Aura's expectations for the estimated patient populations and related market opportunities for bel-sar; and the potential for regulatory approval of 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, 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 preclinical and 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 the 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 United States 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 Contact:
Alex Dasalla
Head of Investor Relations and Corporate Communications
IR@aurabiosciences.com

Media Contact:
Kimberly Ha
KKH Advisors
kimberly.ha@kkhadvisors.com
917-291-5744

Exhibit 99.2

September 2024

Innovating the future of cancer care to cure patients and preserve organ function

aura

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; statements regarding our expectations for an improved quality of life of patients after treatment with bel-sar; 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 commercialize our products, if approved; 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; our expected cash runway into the second half of 2026; and the implementation of our business model, including 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 (SEC), as well as discussions of potential risks, uncertainties, and other important factors in our other subsequent filings with the SEC, which are available on the SEC's website at www.sec.gov. 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 (FDA) 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.

Well positioned with multiple near-term clinical catalysts

Precision therapy platform

Developing a novel class of drugs called virus-like drug conjugates (VDCs)

Direct tumor cell killing and immune activation

Focal treatment approach to deliver durable response

Late-stage clinical development

Phase 3 in primary uveal melanoma ongoing

FDA SPA agreement

Large market opportunity in areas of unmet need

Ocular oncology
>60,000 patients/yr (US/EU)[1–7]

Urologic oncology
~500,000 patients/yr (globally)[8]

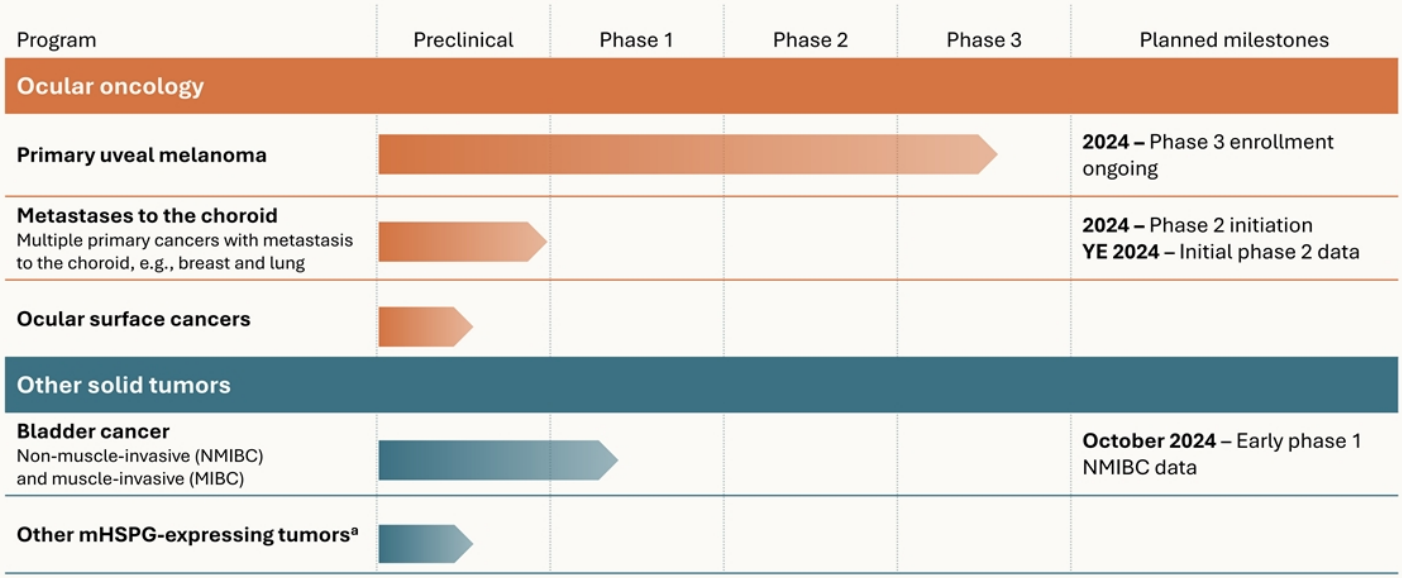
Key upcoming catalysts

Multiple clinical data readouts expected within next 6–12 months, including early phase 1 bladder data

Cash expected to fund operations into 2H 2026

1. Yu G-P et al. *Am J Ophthalmol.* 2003;135(6):800-6. **2.** Triay E et al. *Br J Ophthalmol.* 2009;93(11):1524-8. **3.** Newton R et al. *Lancet.* 1996;347(9013):1450-1. **4.** Dalvin LA. *Br J Ophthalmol.* 2018;102(12):1728-1734. **5.** Sun EC et al. *Cancer Epidemiol Biomarkers Prev.* 1997;6(2):73-7. **6.** Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putman. **7.** American Cancer Society. Key statistics for retinoblastoma. Available at: https://www.cancer.org/cancer/types/retinoblastoma/about/key-statistics.html. Accessed Sept 5, 2024. **8.** Bladder cancer. Putnam & Assoc. Epidemiology Analysis.
FDA, United States Food and Drug Administration; **SPA**, Special Protocol Assessment.

Clinical pipeline across multiple solid tumor indications



[a]Virus-like drug conjugates (VDCs) bind to a subset of modified tumor associated glycosaminoglycans (GAGs) that are part of the heparan sulphate chain of heparan sulfate proteoglycans (HSPGs).[1]

1. Kines RC, and Schiller JT. *Viruses*. 2022;14(8):1656. **mHSPG**, modified heparan sulphate proteoglycan; **MIBC**, muscle invasive bladder cancer; **NMIBC**, non-muscle-invasive bladder cancer; **YE**, year-end.

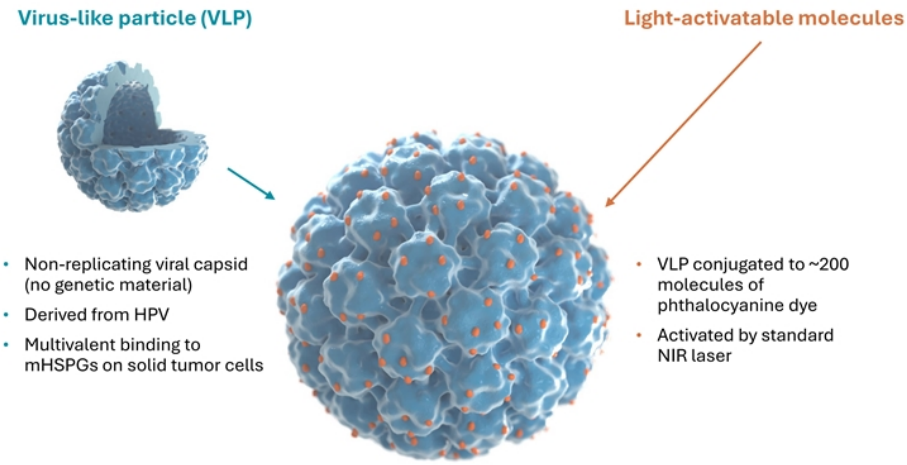
Bel-sar is a potential first-in-class therapy for multiple solid tumors

aura

Bel-sar (AU-011) is a VDC designed with dual specificity to reduce potential for off-target effects:

- Selectively binds to tumor cells (not to local healthy tissue)
- Activated only at site of laser administration

Virus-like drug conjugates (VDCs) are a novel technology platform

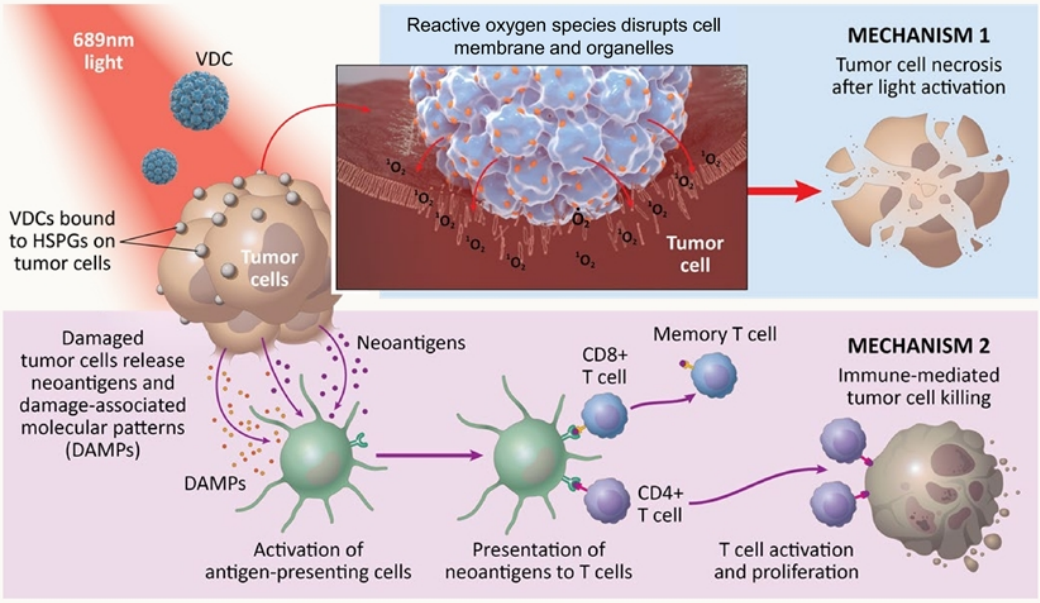


Bel-sar (AU-011)

VDCs selectively deliver direct tumor cell killing and immune activation

Fleury MJJ et al. *Mol Biotechnol.* 2014;56(5):479-86. Kines RC, et al. *Int J Cancer.* 2016;138(4):901–11. Kines RC, et al. *Mol Cancer Ther.* 2018;17(2):565–74. Kines RC, et al. *Cancer Immunol Res.* 2021;9:693–706. **HPV**, human papillomavirus; **mHSPG**, modified heparan sulphate proteoglycan; **NIR**, near infrared; **VDC**, virus-like drug conjugate; **VLP**, virus-like particle. Bel-sar (AU-011) is an investigational product candidate. The effectiveness and safety of bel-sar have not been established, and bel-sar is not approved for use in any jurisdiction.

Bel-sar has a novel dual mechanism of action



Disruption of tumor cell membrane and pro-immunogenic cell death by necrosis

T cell activation and immune-mediated tumor cell killing

Potential key differentiation:

- Genetic mutation-agnostic
- Binding and potency across multiple cancer cell types from different tissue origins

Kines RC, et al. *Int J Cancer*. 2016;138(4):901–11. Kines RC, et al. *Mol Cancer Ther*. 2018;17(2):565–74. Kines RC, et al. *Cancer Immunol Res*. 2021;9:693–706.
DAMPs, damage-associated molecular patterns; **HSPG**, heparan sulfate proteoglycan; **VDC**, virus-like drug conjugate.

Ocular Oncology

Bel-sar target indications:

Primary uveal melanoma | Metastases to the choroid | Ocular surface cancers

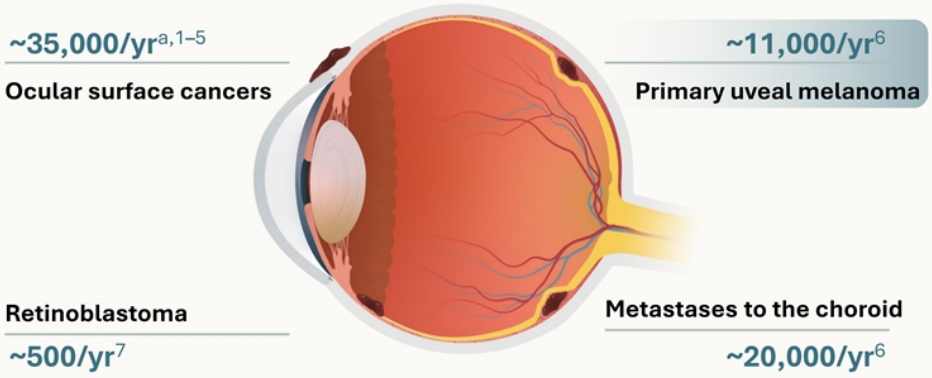
aura

Bel-sar opportunities in ocular oncology represent a multi-billion-dollar addressable market

- With only ~100 ocular oncologists in the US/EU, a global launch may be accomplished with a small (<20) field-based team

~66,000 patients/year

Ocular oncology franchise total addressable market (US/EU)



[a]Includes conjunctival melanoma, primary acquired melanosis, squamous cell carcinoma and ocular surface squamous neoplasia.[1-5]

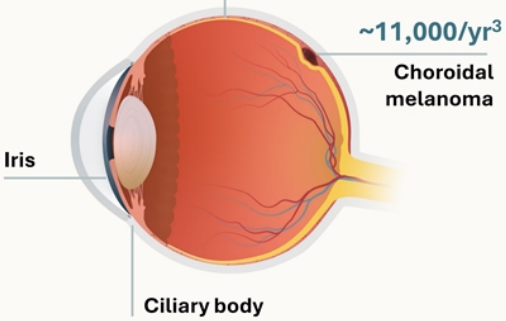
1. Yu G-P et al. *Am J Ophthalmol*. 2003;135(6):800-6. **2.** Triay E et al. *Br J Ophthalmol*. 2009;93(11):1524-8. **3.** Newton R et al. *Lancet*. 1996;347(9013):1450-1. **4.** Dalvin LA. *Br J Ophthalmol*. 2018;102(12):1728-1734. **5.** Sun EC et al. *Cancer Epidemiol Biomarkers Prev*. 1997;6(2):73-7. **6.** Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putman. **7.** American Cancer Society. Key statistics for retinoblastoma. Available at: https://www.cancer.org/cancer/types/retinoblastoma/about/key-statistics.html. Accessed Sept 5, 2024.

Bel-sar (AU-011) is an investigational product candidate. The effectiveness and safety of bel-sar have not been established, and bel-sar is not approved for use in any jurisdiction.

Bel-sar is in phase 3 for primary uveal melanoma, the most common primary intraocular cancer in adults

- Primary uveal melanoma is a high unmet medical need
- With no approved vision-preserving therapies, the current standard-of-care is radiotherapy – treatment that leads to legal blindness[4,5]

Choroid is 90%
of the uvea[1]



Uvea: Choroid, ciliary body and iris

Most common primary intraocular cancer in adults[2,3]

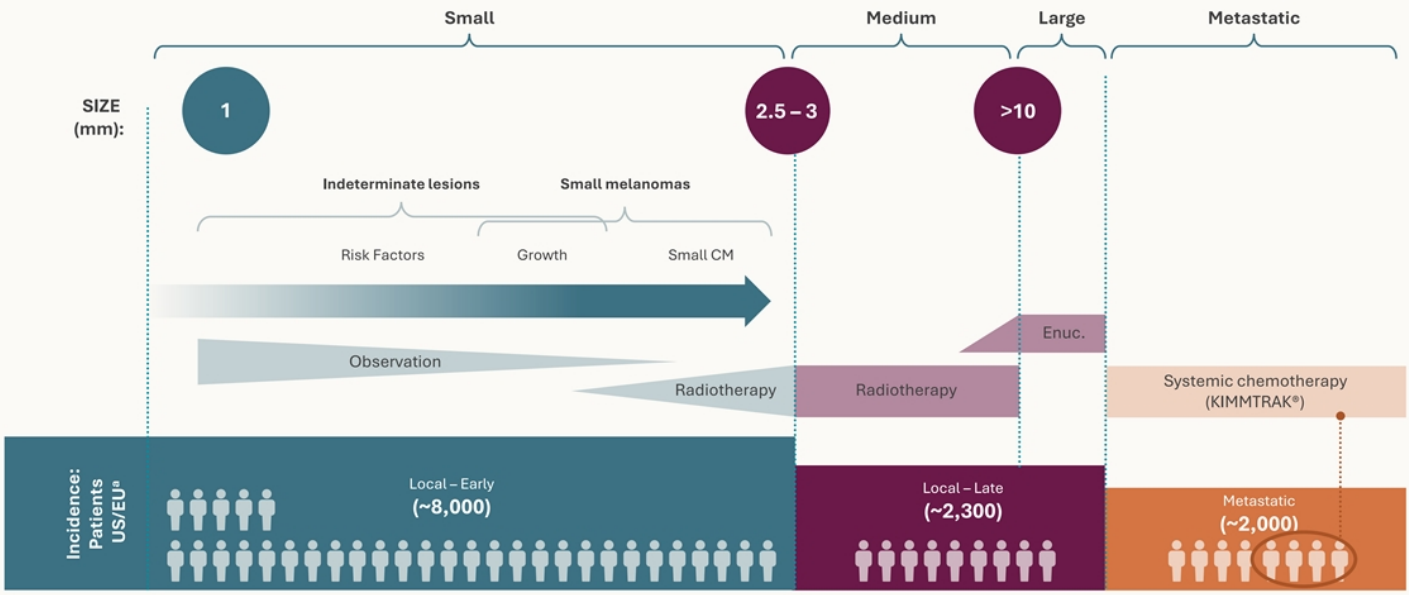
~80% of patients diagnosed with **early-stage disease**[3]

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

Bel-sar has the potential to provide a treatment option that preserves vision

1. Heiting, G. Iris/uvea of the eye. Available at: https://www.allaboutvision.com/en-gb/resources/uvea-iris-choroid/. Accessed Oct. 3, 2023. **2.** Kaliki S and Shields CL. *Eye (Lond)*. 2017;31(2):241-257. **3**. Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putman. **4**. 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. **5**.. 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.

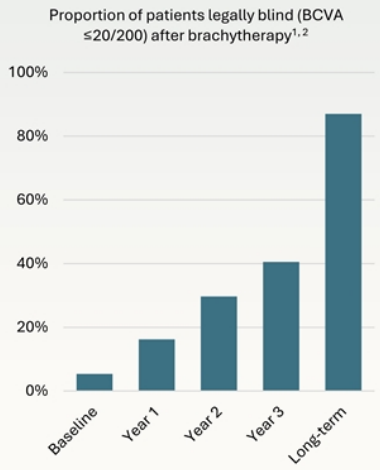
Current treatment paradigm for primary uveal melanoma

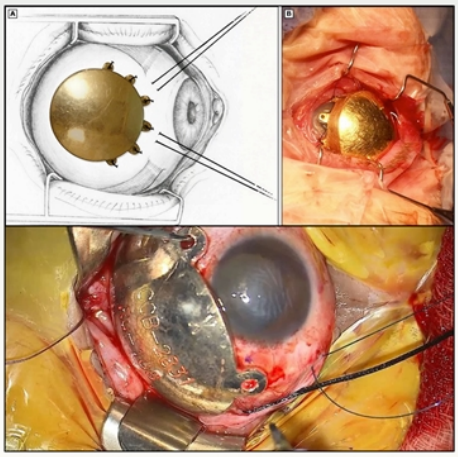


[a]Each figure represents ~250 persons.
Shields CL et al. Choroidal and ciliary body melanoma. Available at: https://eyewiki.aao.org/Choroidal_and_Ciliary_Body_Melanoma Accessed September 9, 2024. Singh AD, et al. *Ophthalmology.* 2005;112(10):1784–89. Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putman. **CM**, choroidal melanoma; **Enuc.**, enucleation.

High morbidity associated with current standard of care

Up to 87% of primary uveal melanoma patients become legally blind over time in the eye treated with radiotherapy[1,2]





	Radiotherapy[3–6]
Adverse Event	
Surgeries secondary to AEs (e.g., cataracts)	40%+
Radiation retinopathy	40%+
Neovascular glaucoma	10%
Dry eye syndrome	20%
Strabismus	2%+
Retinal detachment	1–2%
Vision loss (≥15 letters)	~70%
Long-term legal blindness (≤20/200)	~90%
Serious Adverse Event	
Scleral necrosis	0–5%
Enucleation/eye loss	10–15%
Severe vision loss (≥30 letters) in HRVL	~90%

1. Jarczak J et al. *Medicina (Kaunas).* 2023;59(6):1131. **2.** Tsui I, et al. *Open Ophthalmol J.* 2015;9:131–5. **3.** Shields CL, et al. *Arch Ophthalmol.* 2000;118(9):1219–1228. **4.** Peddada KV, et al. *J Contemp Brachytherapy.* 2019;11(4):392–397. **5.** Shields CL et al. *Curr Opin Ophthalmol.* 2019;30(3):206–214. **6.** Kaliki S, Shields CL. *Eye.* 2017;31(2):241–257. **AE**, adverse event; **BCVA**, best-corrected visual acuity; **HRVL**, high-risk for vision loss.

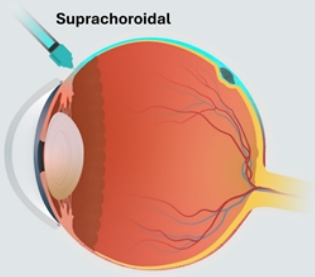
Bel-sar has the potential to be the first approved vision-preserving therapy in primary uveal melanoma

Treatment Goals

- Local tumor control
- Vision preservation
- No radiation-related morbidity
- Reduce metastasis risk with early treatment
- Improve safety and quality of life

In-office procedure

Delivery via suprachoroidal injection



Two injections (2 min. each) 30 min. apart

Light activation with standard ophthalmic laser

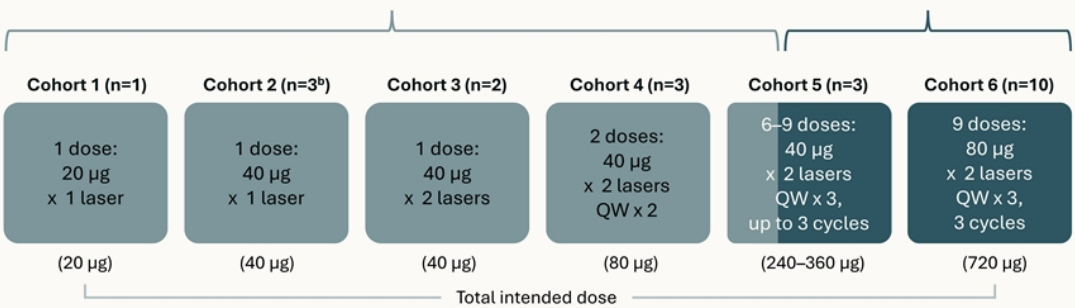
10-30 min. procedure

Bel-sar (AU-011) is an investigational product candidate. The effectiveness and safety of bel-sar have not been established, and bel-sar is not approved for use in any jurisdiction.

Phase 2 trial of bel-sar for choroidal melanoma: Open-label, dose-escalation with suprachoroidal administration

Trial design – 22 participants enrolled

Patient population representative of early-stage disease: Small choroidal melanoma and indeterminate lesions



Endpoints

Tumor progression
Growth in tumor height ≥0.5 mm or ≥1.5 mm in LBD relative to baseline

Visual acuity loss
≥15 letters decrease from baseline

Tumor thickness growth rate
Change in rate of growth of tumor thickness

Goal: To determine safety, optimal dose and therapeutic regimen with suprachoroidal administration

One cycle = Doses on days 1, 8, and 15.
[a]12 patients enrolled, 1 patient who discontinued after 1 cycle due to unrelated SAEs is not included in data analysis (n=11). [b]Cohort 2: 2 participants were planned; third participant was additionally enrolled due to dose error in 1 participant.
LBD, largest basal diameter; **QW,** every week; **SAE,** serious adverse event. ClinicalTrials.gov Identifier, NCT04417530: AU-011-202. **Data on file, Aura Biosciences.**

Baseline characteristics

All study participants

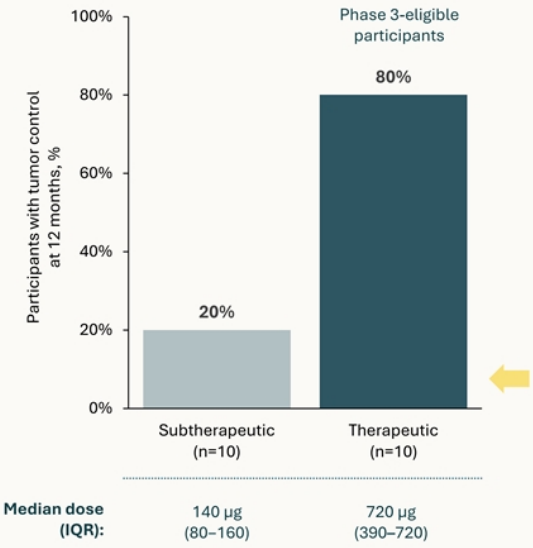
	All patients (n=22)
Female (%)	54.5
White, not Hispanic or Latino (%)	100
Subretinal fluid at screening (%)	100
Orange pigment at screening (%)	86.4
Documented growth prior to screening (%)	86.4 *(100% of therapeutic group)*
Mean age at screening (years, ± SD)	59.2 (±16.5)
Mean baseline BCVA in study eye (ETDRS letters, ± SD)	83.2 (±7.2)
Mean baseline LBD (mm, ± SD)	8.5 (±1.4)
Mean baseline tumor thickness (mm, ± SD)	2.0 (±0.5)
Mean tumor distance to closest vision-critical structure at screening (mm, ± SD)	2.0 (±2.3)
Tumors at high risk for vision loss (%)[a]	73% *(80% [8/10] of therapeutic group)*

[a]High risk for vision loss defined as tumor edge within either 3 mm of foveal center or 3 mm of optic disc edge.
BCVA, best-corrected visual acuity; **ETDRS**, Early Treatment Diabetic Retinopathy Study; **LBD**, largest basal diameter. **Data on file, Aura Biosciences.**

High local complete response rate at 12 months follow-up

80% tumor control rate[a] at 12 months among the 10 phase 3-eligible patients in the 3-cycle cohorts

High tumor control rates with therapeutic regimen in phase 3-eligible patients with active growth

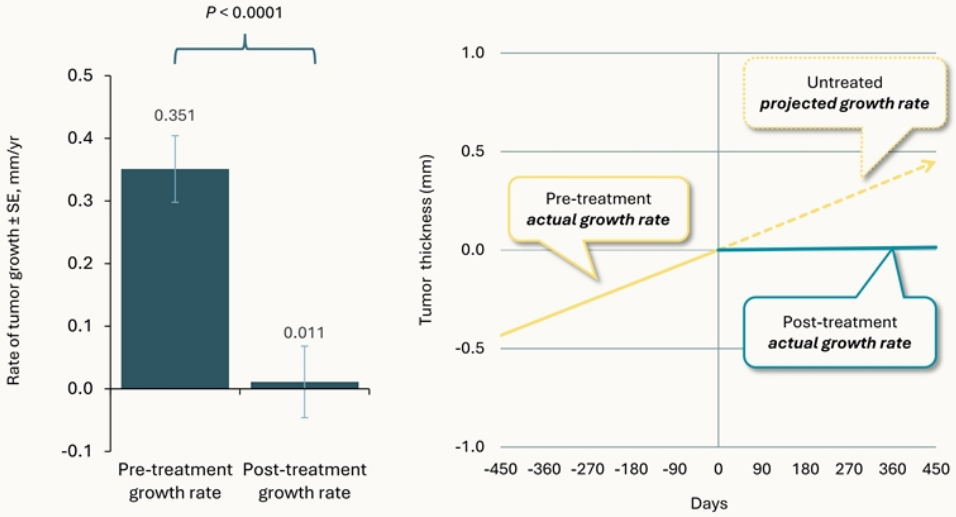


Dose/ Regimen	n	Tumor control rate, %
Subtherapeutic regimen		
≤2 cycles	10	20% (2/10)
Therapeutic regimen		
3 cycles, phase 3-eligible[b]	10	80% (8/10)

[a]Local complete response, or CR, in early-stage choroidal melanoma is described as tumor control and complete arrest of tumor growth by ocular oncologists.
[b]One participant with circumpapillary tumor that did not meet phase 3 criteria is not included.
LBD, largest basal diameter. ClinicalTrials.gov Identifier, NCT04417530: AU-011-202. **Data on file, Aura Biosciences.**

In phase 3-eligible patients, the 3-cycle regimen resulted in cessation of growth among responders (N=8)

Rate of tumor growth with bel-sar treatment

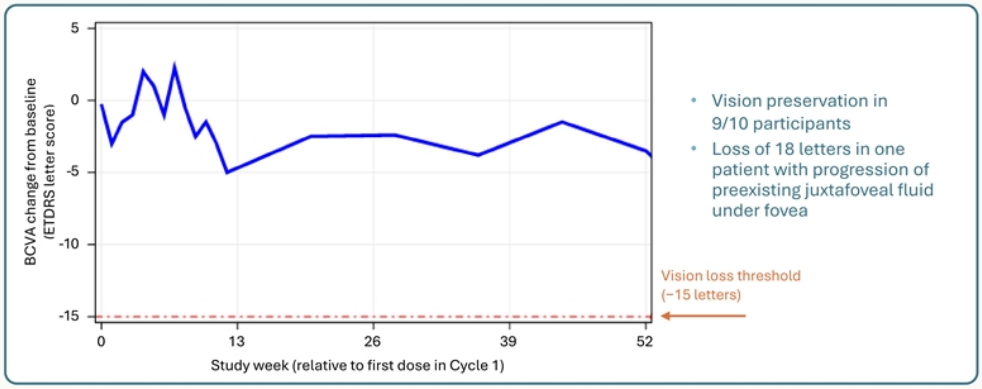


Tumor thickness growth rates/slopes estimated using Mixed Models for Repeat Measures (MMRM); random intercept and slope model for Historical and Study periods. ClinicalTrials.gov Identifier, NCT04417530: AU-011-202. **Data on file, Aura Biosciences.**

Visual acuity was preserved in 90% of phase 3-eligible patients receiving a bel-sar therapeutic regimen

- 80% were at high risk of vision loss with tumors < 3 mm to the fovea or optic nerve
- 90% visual acuity preservation supports the potential for bel-sar to be a front-line therapy for early-stage disease

Median change in BCVA in phase 3-eligible participants with therapeutic regimen (N=10)[a]



Populations	Patients (n)	Vision failures[b] (n)	Vision preservation rate (%)
All dose cohorts			
All treated patients	22	1	95%
Subtherapeutic			
≤2 cycles	10	0	100%
Therapeutic			
3 cycles and phase 3-eligible[a]	10	1	90%

[a]One participant with circumpapillary tumor that did not meet phase 3 criteria is not included. [b]Vision acuity loss defined as ≥15 letters decrease from baseline in ETDRS BCVA letter score.
BCVA, best-corrected visual acuity; **ETDRS,** Early Treatment Diabetic Retinopathy Study.
ClinicalTrials.gov Identifier, NCT04417530: AU-011-202. **Data on file, Aura Biosciences.**

Bel-sar treatment had a favorable safety profile

- No posterior inflammation
- No treatment-related SAEs
- No grade 3–5 treatment-related AEs

Phase 2 safety outcomes (bel-sar/laser-related)

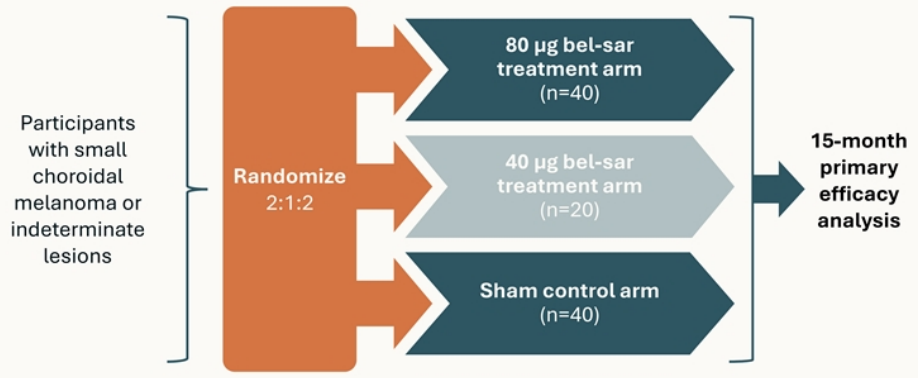
	All treated participants (n=22)*			
Drug/laser-related adverse events	**Grade I**	**Grade II**	**Grade III-V**	**Total**
Anterior chamber inflammation**	4 (18.2%)	0	0	4 (18.2%)
Anterior chamber cell**	2 (9.1%)	0	0	2 (9.1%)
Eye pain	2 (9.1%)	0	0	2 (9.1%)
Anisocoria	1 (4.5%)	0	0	1 (4.5%)
Conjunctival edema	1 (4.5%)	0	0	1 (4.5%)
Cystoid macular edema	1 (4.5%)	0	0	1 (4.5%)
Pupillary reflex impaired	1 (4.5%)	0	0	1 (4.5%)
Salivary gland enlargement	0	1 (4.5%)	0	1 (4.5%)

***Median duration 6 days (IQR: 3–10 days); All resolved with no or minimal treatment; If topical steroids given, median treatment duration 6 days*

* Table presents participants with AEs related to bel-sar or laser by severity and overall; participants with >1 AE are counted in the highest severity group
AE, adverse event; **SAE,** serious adverse event; **IQR,** interquartile range
ClinicalTrials.gov Identifier: NCT04417530; AU-011-202. **Data on file, Aura Biosciences.**

Bel-sar for small choroidal melanoma or indeterminate lesions: Global phase 3 CoMpass trial now enrolling

Target enrollment ~100 participants globally
Anticipated sites in North America, Europe, Middle East and Asia-Pacific Regions



Primary endpoint

Time to tumor progression

Increase in tumor thickness ≥0.5 mm or ≥1.5 mm in LBD

First key secondary endpoint

Time to composite endpoint: Tumor progression or visual acuity failure

Increase in tumor thickness ≥0.5 mm or ≥1.5 mm in LBD **OR** ≥15 decrease in ETDRS-BCVA letter score from baseline

Received **fast track** and **orphan drug designations**
An **SPA agreement** indicates concurrence by the FDA that the design of the trial can adequately support a regulatory submission

BCVA, best-corrected visual acuity; **ETDRS**, Early Treatment Diabetic Retinopathy Study; **LBD**, largest basal diameter; **SPA**, Special Protocol Assessment.
ClinicalTrials.gov Identifier: NCT06007690; AU-011-301.

Phase 2 final data represented using planned phase 3 endpoints

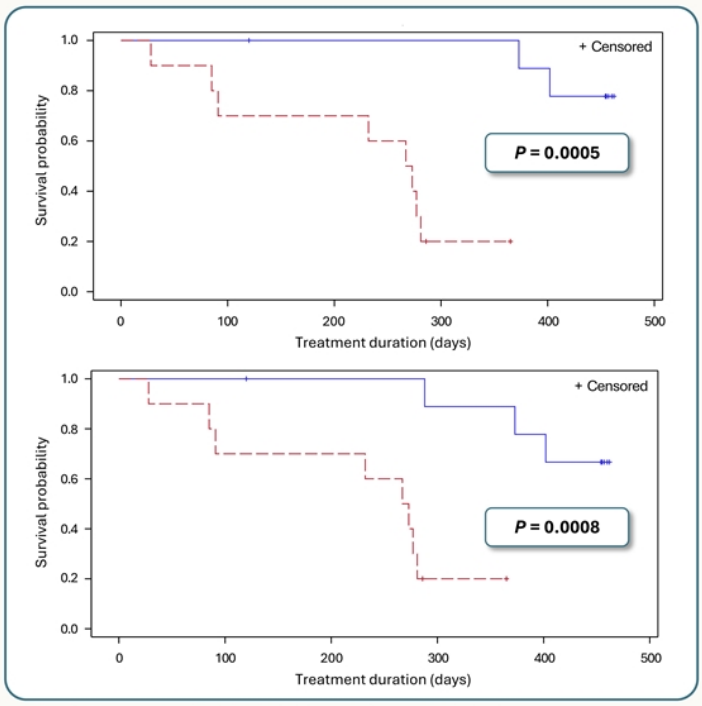
Kaplan-Meier analysis simulation of time-to-event

Time to tumor progression

Change from baseline in thickness ≥0.5 mm; or in LBD ≥1.5 mm confirmed by at least one repeat assessment

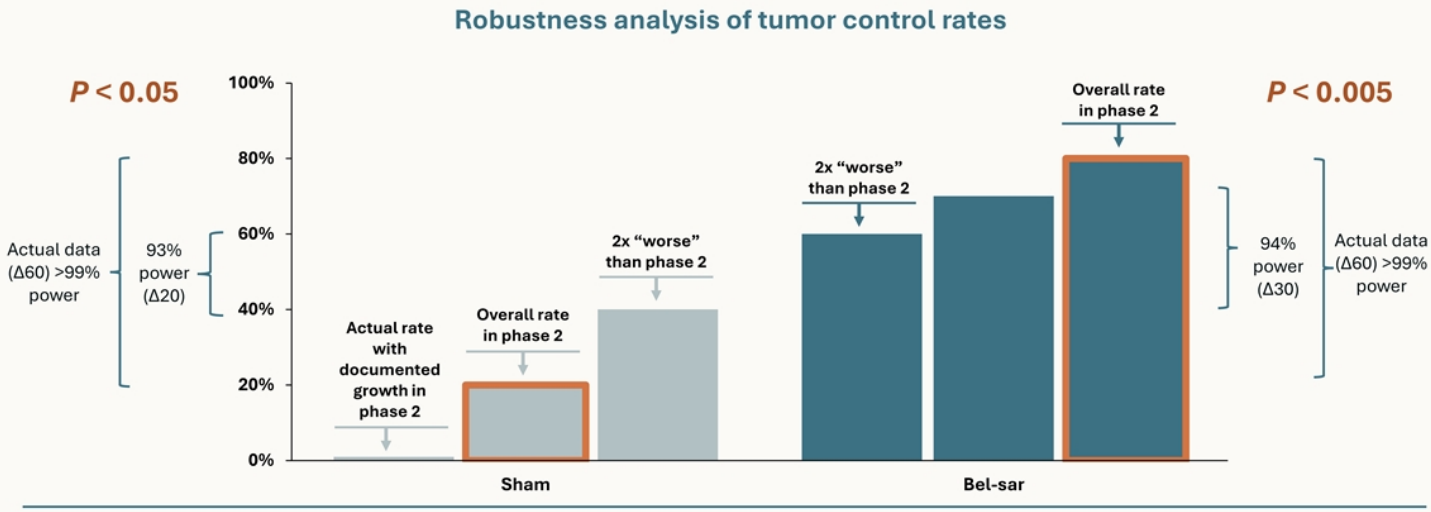
Time to composite endpoint

Time to tumor progression or vision acuity failure (≥15 letter loss in ETDRS-BCVA), whichever occurs earlier



Study duration 12 months. Participants either had an event or were censored at the last visit; some had their Week 52 visit after 365 days. Any events at the final visit are assigned to the actual time of that visit. Log-rank test *p*-value based on unsimulated original Kaplan-Meier curves. **BCVA,** best-corrected visual acuity; **ETDRS,** Early Treatment Diabetic Retinopathy Study; **LBD,** largest basal diameter. ClinicalTrials.gov Identifiers: NCT04417530; AU-011-202 (phase 2); NCT06007690; AU-011-301 (phase 3).
Data on file, Aura Biosciences.

Phase 2 data support phase 3 assumptions



Phase 3 trial design

Same dose, regimen, route of administration, range of tumor sizes, and reading center as phase 2 trial

- Similar population to phase 2 participants receiving the therapeutic regimen
- Enriching for early documented growth; phase 3 randomization stratified by growth rate

ClinicalTrials.gov Identifier: NCT06007690; AU-011-301.

Bel-sar opportunities in ocular oncology represent a multi-billion-dollar addressable market

- With only ~100 ocular oncologists in the US/EU, a global launch may be accomplished with a small (<20) field-based team

~66,000 patients/year

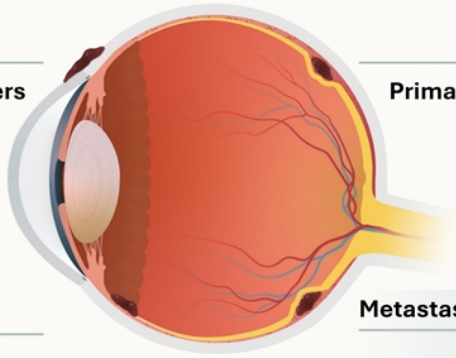
Ocular oncology franchise total addressable market (US/EU)

~35,000/yr[a,1–5]

Ocular surface cancers

~11,000/yr[6]

Primary uveal melanoma



Retinoblastoma

~500/yr[7]

Metastases to the choroid

~20,000/yr[6]

[a]Includes conjunctival melanoma, primary acquired melanosis, squamous cell carcinoma and ocular surface squamous neoplasia.[1-5]

1. Yu G-P et al. *Am J Ophthalmol*. 2003;135(6):800-6. **2.** Triay E et al. *Br J Ophthalmol*. 2009;93(11):1524-8. **3.** Newton R et al. *Lancet*. 1996;347(9013):1450-1. **4.** Dalvin LA. *Br J Ophthalmol*. 2018;102(12):1728-1734. **5.** Sun EC et al. *Cancer Epidemiol Biomarkers Prev*. 1997;6(2):73-7. **6.** Epidemiology analysis for choroidal melanoma and choroidal metastasis by ClearView Healthcare Partners and Putman. **7.** American Cancer Society. Key statistics for retinoblastoma. Available at: https://www.cancer.org/cancer/types/retinoblastoma/about/key-statistics.html. Accessed Sept 5, 2024.

Bel-sar (AU-011) is an investigational product candidate. The effectiveness and safety of bel-sar have not been established, and bel-sar is not approved for use in any jurisdiction.

Metastases to the choroid: Phase 2 trial expected to begin in 2024

Planned Study Design (n=12*)

Study Objectives

- Safety/dose-limiting toxicity
- Efficacy
  - Change in tumor size
  - Change in vision letter score

Study Population

- Patients with unilateral, unifocal metastases to the choroid
- Breast or lung primary
- No changes in concurrent systemic medications planned

Highlights: Primary endpoint at one-month post-treatment; possibility to see tumor shrinkage and vision improvement

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

Urologic Oncology

Bel-sar target indications:

Non-muscle-invasive bladder cancer | Muscle-invasive bladder cancer

aura

Bladder cancer is a global high unmet medical need

~500,000

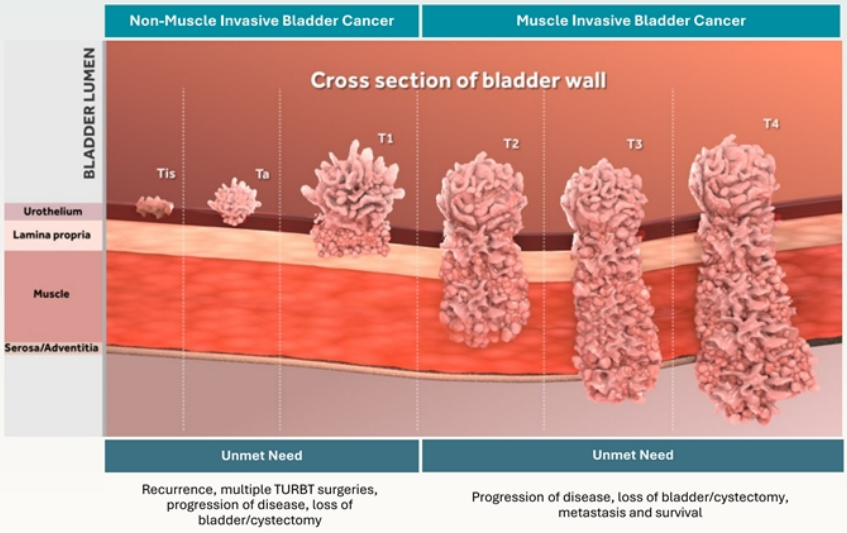
New cases/ year globally[1]

>200,000 NMIBC

New cases/year US, Europe & Asia[1]

>60,000 MIBC

New cases/year US, Europe & Asia[1]

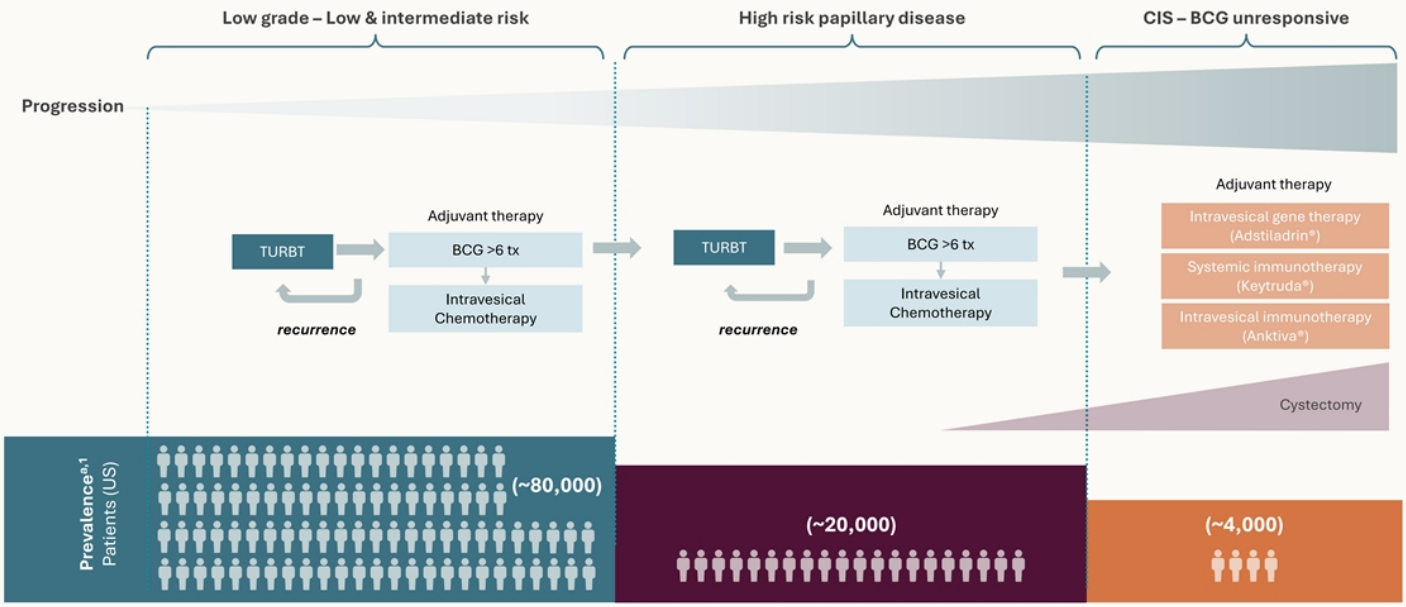


Recurrence, multiple TURBT surgeries, progression of disease, loss of bladder/cystectomy

Progression of disease, loss of bladder/cystectomy, metastasis and survival

1. Bladder cancer. Putnam & Assoc. Epidemiology Analysis.
MIBC, muscle-invasive bladder cancer. **NMIBC**, non-muscle-invasive bladder cancer; **TURBT**, transurethral resection of the bladder.

Current treatment paradigm for bladder cancer



[a]Each figure represents 1000 persons.

1. Holzbeierlein JM et al. *J Urol.* 2024;212(1):3–10. Holzbeierlein JM et al. *J Urol.* 2024 Apr;211(4):533-538. Internal Aura epidemiology of market size data on file.

BCG, Bacillus Calmette-Guérin; CIS, carcinoma in situ; TURBT, transurethral resection of the bladder.

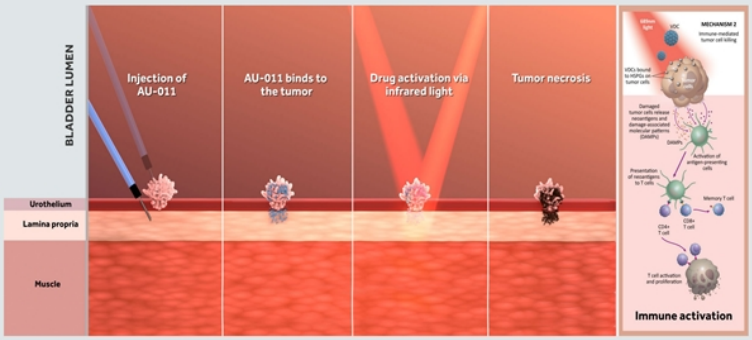
Bel-sar has the potential to be a front-line therapy

Bel-sar can potentially decrease risk of recurrence, reduce need for chemotherapy, and prevent bladder loss

Treatment Goals

- Focal treatment with direct tumor cell killing
- Stimulate anti-tumor specific T cell response
- Reduce risk of recurrence
- Avoid TURBT / operating room
- Improvement in safety and quality of life

In-office procedure



Local administration and light activation with standard cystoscope

MIBC, muscle invasive bladder cancer; **NMIBC,** non–muscle-invasive bladder cancer; **TURBT,** transurethral resection of the bladder.

Bel-sar as potential front-line therapy in NMIBC may be optimized for in office-based procedure

Bel-sar has a dual mechanism of action and its local administration is aligned with clinical practice

Bel-sar's local administration aligned with current urologic oncology practice

- No virus replication or viral shedding
- Lasers and bladder injections (e.g. botox) are commonly used

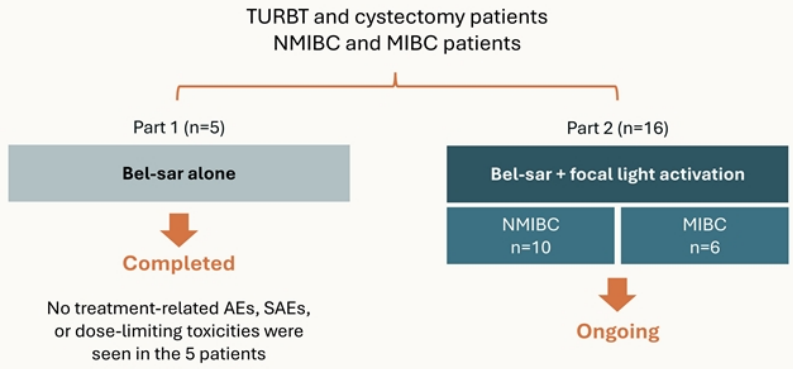
Goals of treatment with bel-sar

- Focal treatment with direct tumor cell killing
- Stimulate anti-tumor specific t-cell response
- Reduce risk of recurrence
- Avoid TURBT / operatingroom

NMIBC, non–muscle-invasive bladder cancer; **TURBT,** transurethral resection of the bladder.

Phase 1 trial for bladder cancer designed to evaluate safety, feasibility, and MoA

21 participants



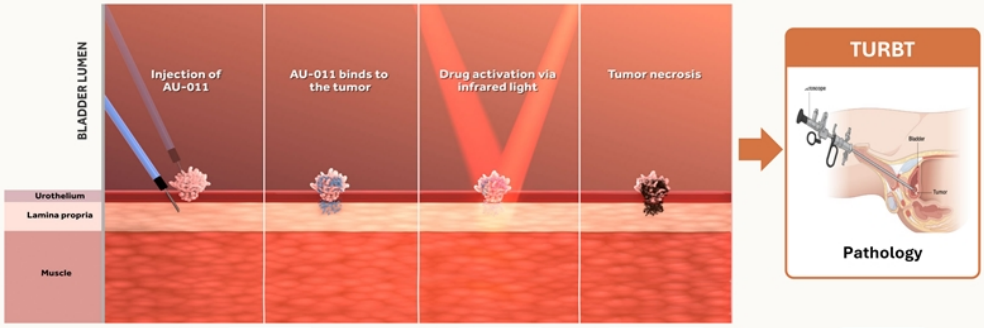
Study objectives

Safety & dose-limiting toxicity	Feasibility of technique	Focal distribution of bel-sar	Focal necrosis	Markers of immune activation

AE, adverse event; **MIBC,** muscle invasive bladder cancer; **MoA,** mechanism of action; **NMIBC,** non–muscle invasive bladder cancer; **SAE,** serious adverse event; **TURBT,** transurethral resection of bladder tumor.
Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Clinical complete response with immune activation after single dose confirmed by histopathology

Phase 1 preliminary data: Light-activated cohort (n=1)



Day 1

- Diagnostic pathology shows non-invasive, low grade urothelial carcinoma
- Injection of bel-sar (100 ug) performed within tumor and below tumor
- Aura present with urologist

Day 2

- Urologist performs light activation with 689 nm infrared light (75 J/cm^2)
- ~5 min duration
- Aura present with urologist

Day 3–7

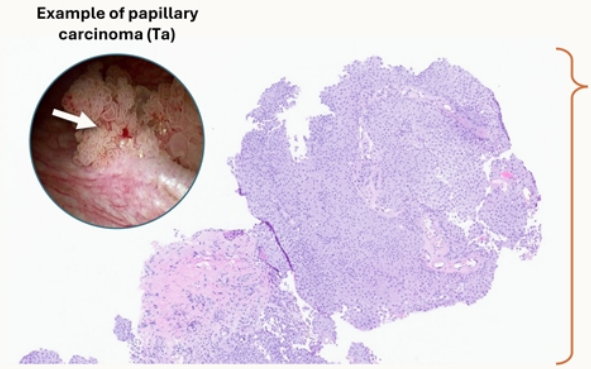
Day 9

- Urologist performs TURBT in area where tumor used to be present
- Pathology shows denuded urothelial mucosa, no cancer cells; focal ulcer and chronic inflammation (eosinophils/lymphocytes)

TURBT, transurethral resection of the bladder. Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

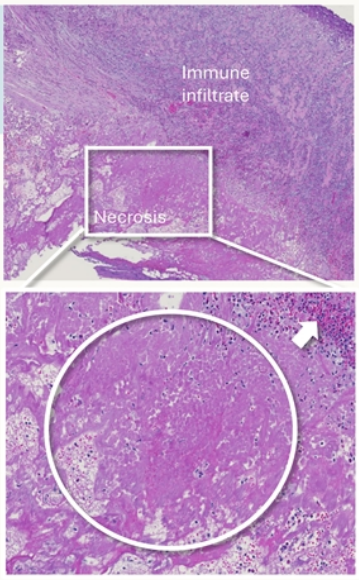
Clinical complete response with immune activation after single dose confirmed by histopathology (part 2; first patient)

Evidence of complete response by absence of tumor cells, as well as immune activation, after single dose treatment in first patient



Papillary urothelial carcinoma

7 days after bel-sar treatment



H&E stain

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

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

H&E, hematoxylin and eosin; **TURBT,** transurethral resection of the bladder. Clinicaltrials.gov identifier: NCT05483868; AU-011-102.

Company highlights

Corporate

- **Strong cash position** – expected to fund operations into **2H 2026**
- **Experienced leadership** team across functions

Urologic Oncology Therapeutic Area

- Phase 1 trial - clinical complete response in first patient with single dose
- Company expects to present early NMIBC data from ongoing phase 1 trial at a urologic oncology investor event in October 2024

Ocular Oncology Therapeutic Area

Primary uveal melanoma

- **Global phase 3 CoMpass** trial actively enrolling
- **Special Protocol Assessment (SPA)** agreement with FDA
- Phase 3 assumptions **supported by phase 2 data**

Metastases to the choroid

- **Phase 2** trial planned to initiate **in 2024**
- Second ocular indication **potentially doubles market opportunity**[1]
- **Initial data** expected by year **end 2024**

1. ClearView & Putnam & Assoc. Epidemiology Analysis Choroidal Melanoma and Choroidal Metastasis. **FDA**, United States Food and Drug Administration. **NMIBC**, non-muscle-invasive bladder cancer. Bel-sar (AU-011) is an investigational product candidate. The effectiveness and safety of bel-sar have not been established, and bel-sar is not approved for use in any jurisdiction.