

**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): June 19, 2022

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

Delaware
(State or other jurisdiction
of incorporation)

001-40971
(Commission
File Number)

32-0271970
(I.R.S. Employer
Identification No.)

85 Bolton Street
Cambridge, Massachusetts
(Address of principal executive offices)

02140
(Zip Code)

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

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company

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

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

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

Item 7.01 Regulation FD Disclosure.

On June 22, 2022, Aura Biosciences, Inc. (the "Company") issued a press release titled "Aura Biosciences Reports Topline Data from a Retrospective Study of Belzupacap Sarotalocan (AU-011) versus Radiotherapy Supporting the Value of a Vision Preserving Therapy for the Treatment of Patients with Early-Stage Choroidal Melanoma." The Company presented the data at the 20th congress of the International Society of Ocular Oncology on June 19, 2022. A copy of the press release and a copy of the presentation are attached as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibits 99.1 and 99.2, 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 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by the Company, dated June 22, 2022, furnished herewith.
99.2	Aura Biosciences, Inc. 2022 ISOO Presentation, dated June 19, 2022, furnished herewith.
104	Cover Page Interactive Data (embedded within the Inline XBRL document)

SIGNATURES

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

Date: June 22, 2022

AURA BIOSCIENCES, INC.

By: /s/ Elisabet de los Pinos
Elisabet de los Pinos, Ph.D.
President and Chief Executive Officer



Aura Biosciences Reports Topline Data from a Retrospective Study of Belzupacap Sarotalocan (AU-011) versus Plaque Radiotherapy Supporting the Value of a Vision Preserving Therapy for the Treatment of Patients with Early-Stage Choroidal Melanoma

In this Retrospective Matched Case Control Study, Belzupacap Sarotalocan Achieved Statistically Significant Vision Preservation Compared to Plaque Radiotherapy, the Current Standard of Care

CAMBRIDGE, MA – June 22, 2022 – 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, reported results from a retrospective, matched case control study. This retrospective analysis assessed the visual acuity of patients following treatment with plaque radiotherapy compared with prospective data on visual acuity in subjects with early-stage choroidal melanoma treated with belzupacap sarotalocan by intravitreal administration in the Phase 1b/2 trial (NCT03052127).

“These results point to the high unmet medical need for a first line vision preserving therapy for the treatment of early-stage choroidal melanoma given the high levels of irreversible visual acuity loss with the current standard of care with radiotherapy,” said Carol Shields, MD, Chief of the Ocular Oncology Service at Wills Eye Hospital and Professor of Ophthalmology at Thomas Jefferson University. “Being able to treat the disease early, avoid radiotherapy and spare long-term vision loss in many patients, as well as potentially reducing the risk of metastatic disease, could represent a paradigm shift in our approach to the treatment of choroidal melanoma. This would be a significant improvement in the quality of life for patients with this life-threatening rare disease.”

Results from the Retrospective Study

Study Design

This retrospective, matched case control study compared visual acuity outcomes for 43 patients from Aura’s Phase 1b/2 trial evaluating intravitreal administration of belzupacap sarotalocan in patients with early-stage choroidal melanoma (AU-011-101, NCT03052127) to 150 patients from the subject database of a previously completed and published study where patients with small choroidal melanoma had been treated with plaque radiotherapy (Shields, et al. “[Visual Outcome and Millimeter Incremental Risk of Metastasis in 1780 Patients With Small Choroidal Melanoma Managed by Plaque Radiotherapy](#).” *JAMA Ophthalmology*, September 27, 2018). Both cohorts of patients were at high risk for vision loss due to having the tumor edge within 3.0 mm of the fovea. The patients were matched for tumor height, tumor diameter, distance from the fovea and baseline visual acuity, which are among the core factors that impact visual acuity after treatment.



Key Findings:

- The vision results of patients with early-stage choroidal melanoma treated with radiotherapy showed the long term, progressive and irreversible loss of visual acuity in patients where tumors were close to the fovea.
- The loss of vision in radiotherapy patients was ≥ 3 lines in a majority of patients as early as 2 years and ≥ 6 lines as early as 3 years.
- We believe the comparison of the belzupacap sarotalocan and radiotherapy results supports the potential benefit of a targeted treatment achieving a statistically significant difference in visual acuity preservation as soon as two years including for both logMAR (Logarithm of the Minimum Angle of Resolution) vision ($p = 0.0094$) and change in logMAR vision ($p = 0.0323$).
- We believe the progressive loss of visual acuity with radiotherapy observed in this retrospective study underscores the urgent need for a vision preserving targeted therapy.
- The findings of this retrospective study were consistent with published clinical data supporting the irreversible loss of visual acuity after treatment with radiotherapy.

"We are committed to developing the first potential targeted therapy for patients with early-stage choroidal melanoma. We believe the visual acuity results of the retrospective matched case control study are exciting because they support the high unmet medical need for a long-term vision preserving therapy," said Dr. Cadmus Rich, Chief Medical Officer and Head of R&D of Aura Biosciences. "Belzupacap sarotalocan is currently being evaluated in a Phase 2 dose escalation clinical trial (AU-011-202, NCT04417530) using suprachoroidal administration in patients with early-stage choroidal melanoma. We remain on track to initiate our pivotal trial by the end of 2022."

Study Limitations include the retrospective nature and utilizing a matched case control design. The mean follow-up for patients treated with belzupacap sarotalocan in this initial analysis was 15.6 months. Due to the retrospective nature of this analysis, it is hypothesis-generating; no formal conclusions can be drawn. Aura has also initiated a prospective matched case control study to further evaluate the long-term visual acuity results of belzupacap sarotalocan from the Phase 2 trial AU-011-202 using suprachoroidal administration versus radiotherapy.



About Aura Biosciences

Aura Biosciences, Inc. is a clinical-stage biotechnology company developing virus-like drug conjugates (VDCs), a novel class of therapies, for the treatment of multiple oncology indications. Aura's lead VDC candidate, AU-011 (belzupacap sarotalocan), consists of a virus-like particle conjugated with an anti-cancer agent. Belzupacap sarotalocan selectively targets and destroys cancer cells and activates the immune system with the potential to create long-lasting anti-tumor immunity. Belzupacap sarotalocan is currently in development for ocular cancers, with an ongoing Phase 2 dose escalation clinical trial evaluating first-line treatment of choroidal melanoma, a vision- and life-threatening form of eye cancer where standard of care with radiotherapy leaves patients with severe comorbidities, including major vision loss. Aura plans to pursue development of belzupacap sarotalocan across its ocular oncology franchise including for the treatment of patients with choroidal metastases. In addition, leveraging Aura's technology platform, Aura is developing belzupacap sarotalocan more broadly across multiple cancers, starting with a planned Phase 1 clinical trial in patients with non-muscle invasive bladder cancer (NMIBC). Aura is headquartered in Cambridge, MA.

For more information, visit aurabiosciences.com, or follow us on [Twitter](#) and [LinkedIn](#).

Forward Looking Statement

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 belzupacap sarotalocan for the treatment of cancers including choroidal melanoma and NMIBC and expectations with respect to the clinical development of belzupacap sarotalocan.



The forward-looking statements in this press release are neither promises nor guarantees, and investors should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Aura's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including, without limitation, an improved quality of life of patients after treatment with belzupacap sarotalocan; a potential paradigm shift in the approach to the treatment of choroidal melanoma; the urgent need for a vision preserving targeted therapy; the potential of belzupacap sarotalocan compared to the existing standard of care for patients with choroidal melanoma; uncertainties inherent in clinical trials and in the availability and timing of data from ongoing clinical trials; the expected timing for submissions for regulatory approval or review by governmental authorities; the risk that the results of Aura's clinical trials may not be predictive of future results in connection with future clinical trials; whether Aura will receive regulatory approvals to conduct trials or to market products; whether Aura's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; risks, assumptions and uncertainties regarding the impact of the continuing COVID-19 pandemic on Aura's business, operations, strategy, goals and anticipated timelines; Aura's ongoing and planned pre-clinical activities; and Aura's ability to initiate, enroll, conduct or complete ongoing and planned clinical trials. These risks, uncertainties, and other factors include those risks and uncertainties described under the heading "Risk Factors" in Aura's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Aura with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Aura disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Aura's current expectations and speak only as of the date hereof and no representations or warranties (express or implied) are made about the accuracy of any such forward-looking statements.

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ISOO 2022

New Developments in belzupacap
sarotalocan (AU-011),
an Investigational Virus-Like Drug
Conjugate (VDC)
in Ocular Oncology

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Legal Disclosure

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

Except as otherwise noted, these forward-looking statements speak only as of the date of this presentation, and we undertake no obligation to update or revise any of such statements to reflect events or circumstances occurring after this presentation. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. 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.

Aura is
Dedicated to
Science and
Supports
Collaborative
Research



Martine Jager, MD, PhD
Professor of Ophthalmology
Leiden University



Ruben Huis in 't Veld, MSc
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Cadmus Rich, MD
Chief Medical Officer,
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Anneli Savinainen, MS
VP, Head of
Preclinical R&D
Aura Biosciences



Rhonda Kines, PhD
Principal Scientist
Aura Biosciences

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Novel Oncology Platform Using Virus-Like Drug Conjugates (VDCs)

Ocular Oncology

- Opportunity to develop vision preserving therapy for early-stage choroidal melanoma

Foundational Value

- Completed Phase 1b/2 trial: Positive data in key clinical endpoints
- FDA/EMA/MHRA are in alignment with pivotal trial design

Oncology Pipeline

- Solid tumor development programs
- Platform to develop additional VDCs

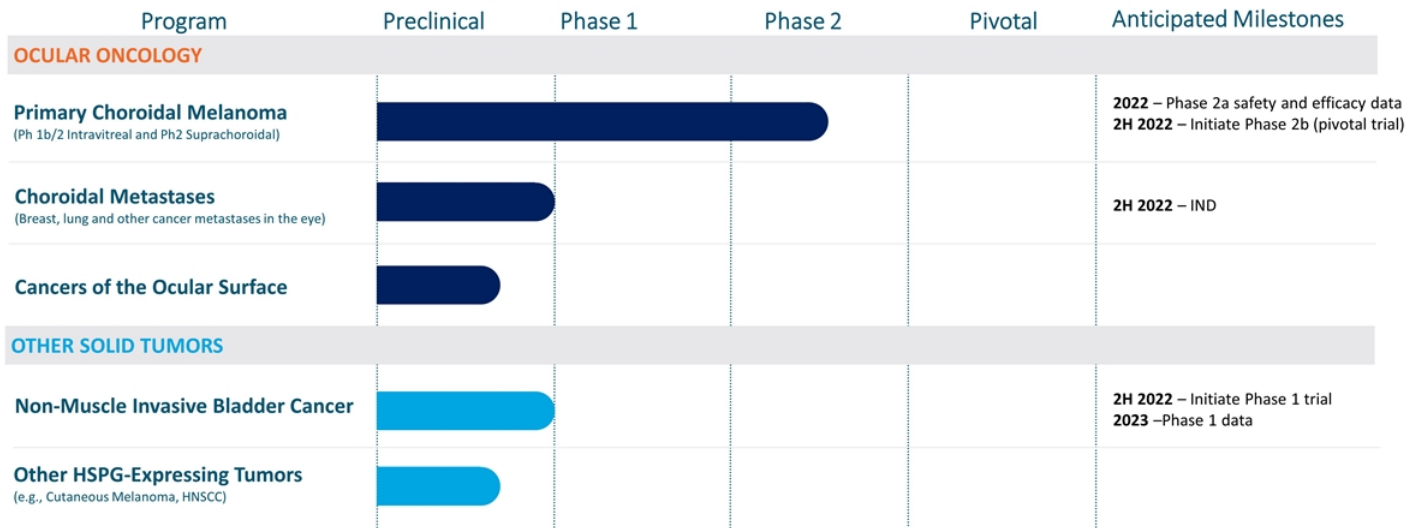
Anticipated Milestones in Ocular Oncology

- Retrospective vision data versus radiotherapy
- Phase 2 Choroidal Melanoma safety and efficacy data
- Initiate Pivotal Trial in Choroidal Melanoma
- IND filing in Choroidal Metastases

Public Company

- Successful IPO 2021

Pipeline Targeting Life-Threatening Cancers with High Unmet Needs



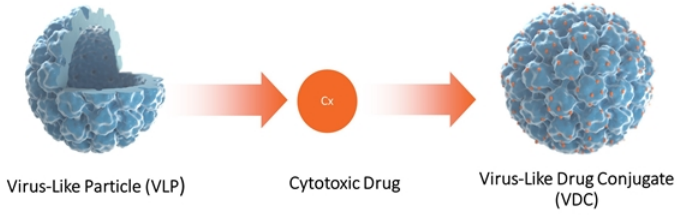
Global Planning for All Product Candidate Indications

Choroidal Metastasis

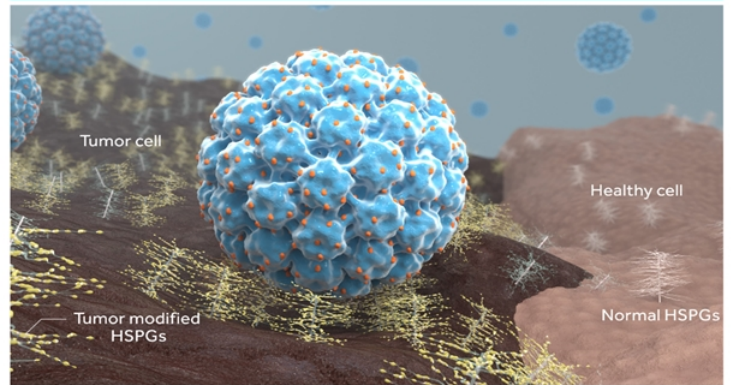


Targeted Oncology Platform - Virus-Like Drug Conjugates (VDCs)

Virus-Like Particles Conjugated to a Cytotoxic Payload to form the VDC



VDCs can Recognize Tumor Associated HSPGs*

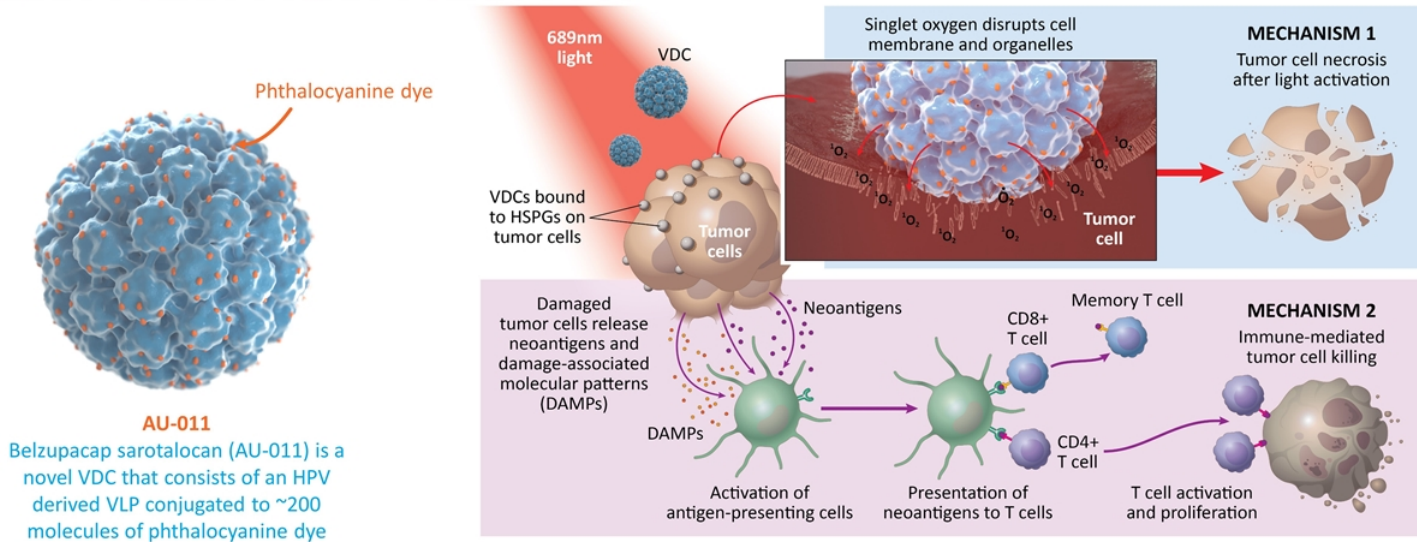


Technology Platform Designed to Target a Broad Range of Solid Tumors Based on Virus-Like Particles with Multiple Options for Cytotoxic Payloads

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

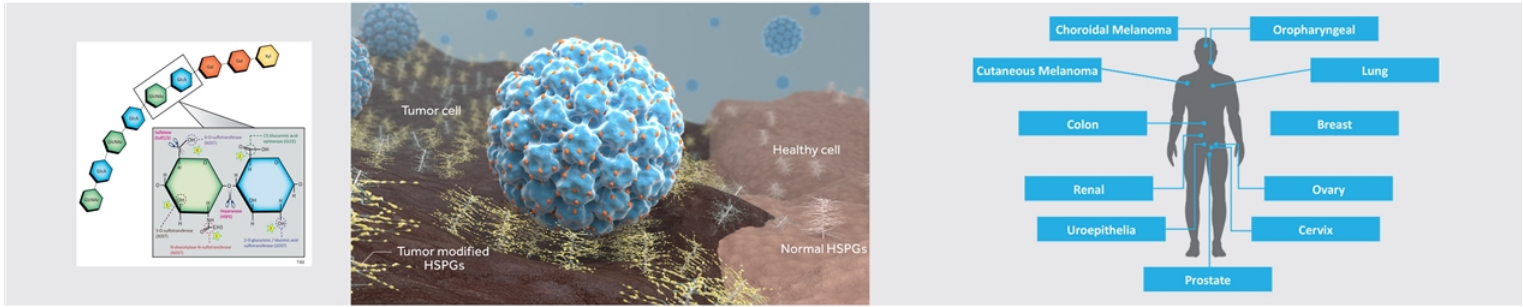
* HSPGs - Heparan Sulphate Proteoglycans

Belzupacap Sarotalocan (AU-011) is an Investigational VDC with a Novel Dual Mechanism of Action



AU-011 Demonstrated Positive Data in Phase 1b/2 Trial in Choroidal Melanoma

Potential to Target Tumors That Express HSPGs



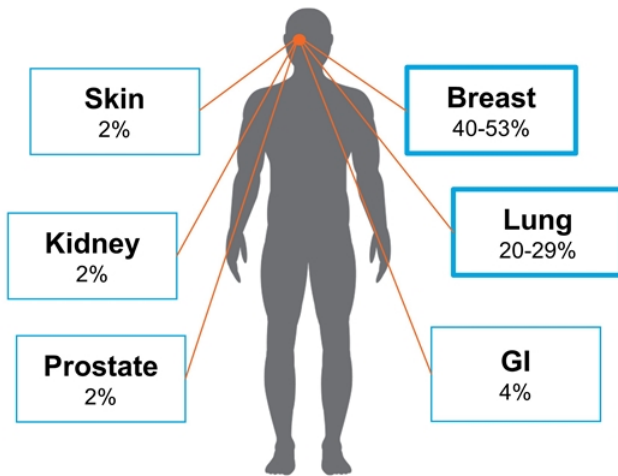
- Heparan sulfate proteoglycans (HSPGs) are a large family of molecules found in the extracellular matrix (ECM) and on the membranes of cells
- Tumors specifically modify HSPGs with key sulfation modifications that provide high binding specificity to a number of ligands
- Tumor modified HSPGs regulate many aspects of tumor progression, including proliferation, invasion, angiogenesis and metastases
- Our VLPs can selectively bind to tumor modified HSPGs and not to normal cells

Broad-based Tumor Targeting Mechanism by Virtue of the Binding to Tumor Specific HSPGs

Knelson et al., Trends in Biochemical Sciences 2014; Fuster and Esko, Nature Reviews Cancer, 2005; Blackhall et al., British Journal of Cancer (2001) 85(8), 1094–1098; Kines et al., International Journal of Cancer, 138;901–911, February 2016; Kines et al., Molecular Cancer Therapeutics, 17(2) February 2018

Choroidal Metastasis – Background

C-Mets Originates from Multiple Primary Cancers¹

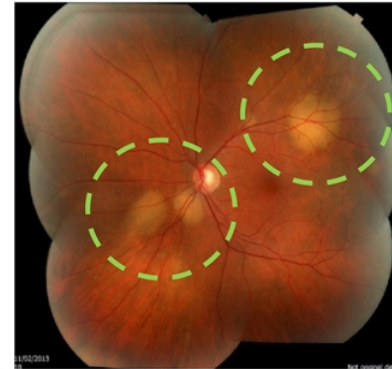


~20K eyes with choroidal metastases in the U.S. annually²

¹Mathis et al. New concepts...choroidal metastasis, *Progress in retinal and eye research* (2019), ²Cohen, Ocular metastasis, *Eye* (2014), ³Shields et al. Survey of 520 eyes with uveal metastases. *Ophthalmology* (1997), ⁴Namad et al. Bilateral choroidal metastasis from non-small lung cancer, *Case reports in oncological medicine* (2014).

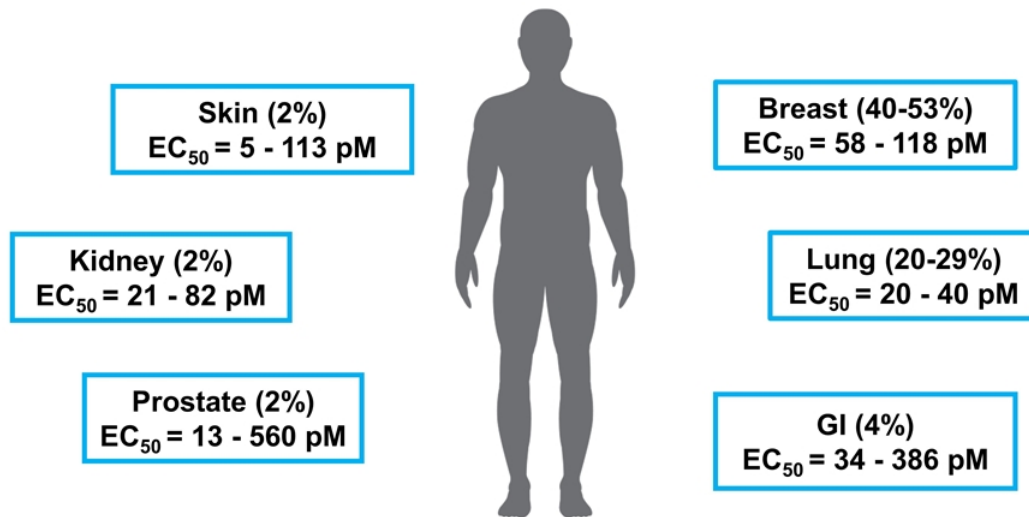
Common Features of C-Mets³

- Unilateral (72%)
- Solitary (72%)
- Choroidal location (88%)



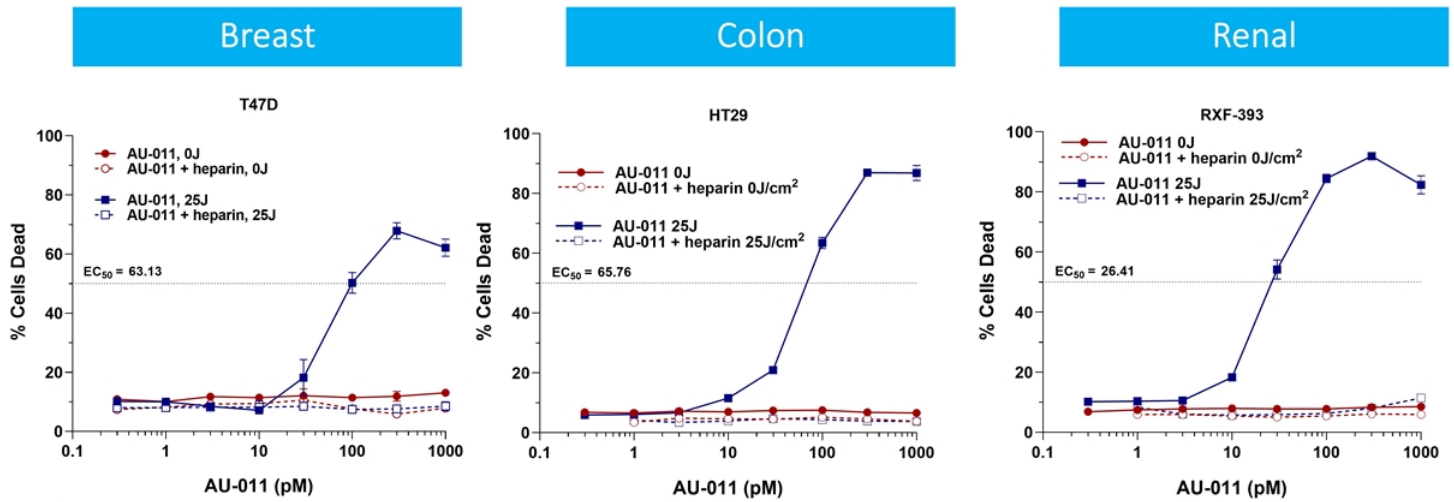
Choroidal Metastasis from non-small cell lung cancer⁴

AU-011 Induced Potent Cytotoxicity in Multiple Human Cancer Cell Lines Commonly Causing Choroidal Metastasis



AU-011 induced potent cell killing upon light activation with potencies (EC_{50} 's) in the picomolar range

AU-011 Demonstrated Binding and Potent Cytotoxicity in Multiple Human Cancer Cell Lines Commonly Causing Choroidal Metastasis

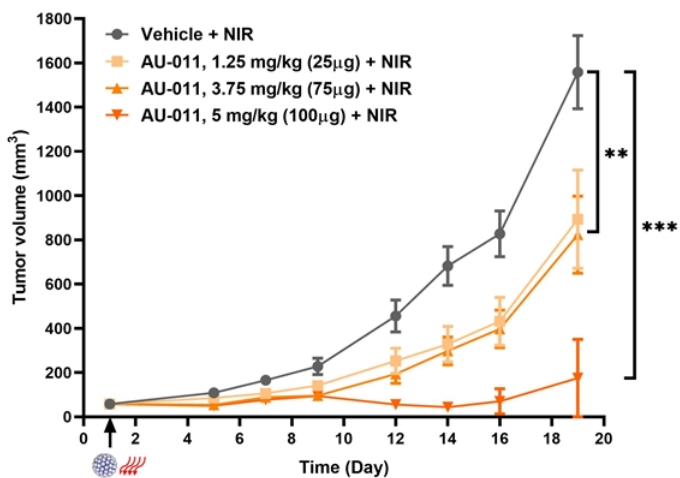


- AU-011 can bind to cancer cells and induced potent cell killing upon light activation
- Specificity was demonstrated by inhibition of HSPG's binding by heparin
- AU-011 demonstrated no cytotoxicity in the absence of light activation

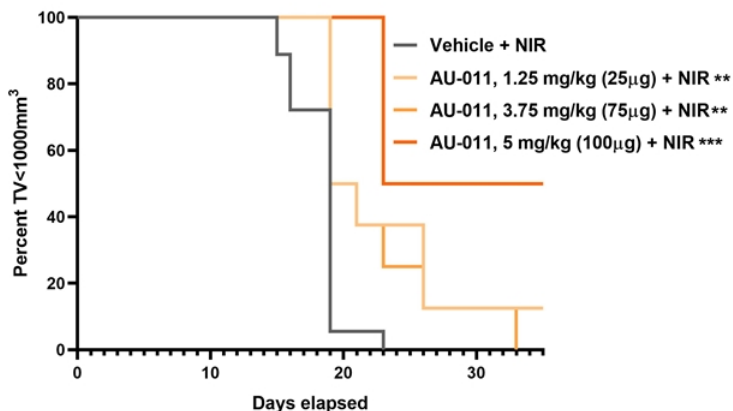
Single Administration of AU-011 Inhibited Tumor Growth and Prolonged Survival in a Dose-Dependent Fashion – Breast Cancer

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

Reduced Tumor Growth



Prolonged Survival



Tumor cells were implanted subcutaneously. AU-011 treatment was initiated when tumors reached approximately 50 mm³. Treatment consisted of a single intravenous administration of AU-011 followed 12 hours later by light activation (400 mW/cm², 58 J/cm²). Tumor volumes were measured over time (N=8-12)

Conclusion

- AU-011 can bind to, and kill, tumor cells derived from the most common cancer types known to metastasize to the choroid
 - Binds to modified HSPG's on the surface of cancer cells
 - No cytotoxicity in the absence of light activation was observed
- AU-011 showed dose-dependent activity in vivo using syngeneic mouse models for cancer types known to metastasize to the choroid
 - Significantly inhibits tumor growth and prolongs survival
 - Statistically significant results in multiple tumor models

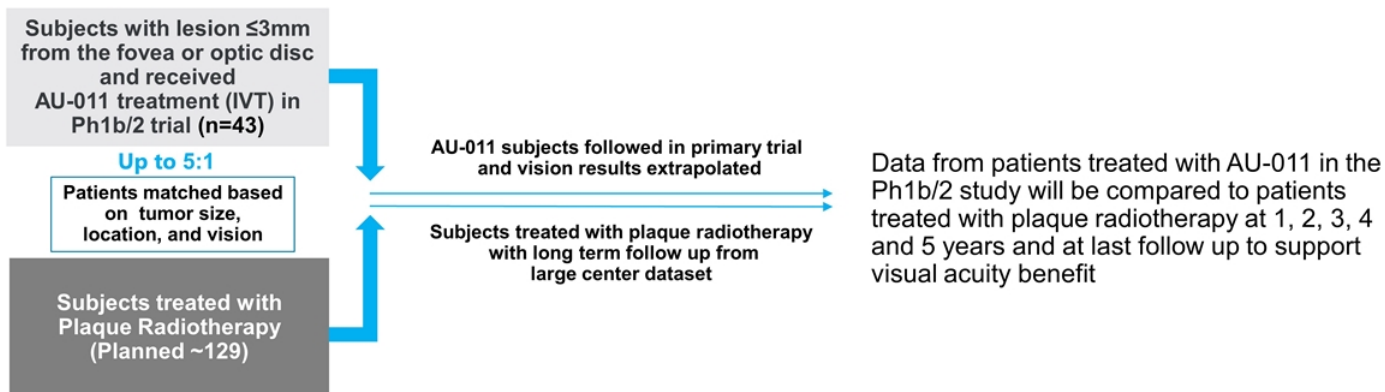
Study results support further evaluation of AU-011 as a potential treatment for choroidal metastasis

Retrospective Matched Case-Control Study



rMCC* Study to Evaluate Visual Acuity Outcomes of AU-011 vs. Plaque Radiotherapy

- Matching criteria: baseline tumor thickness, LBD, distance to fovea/ optic disk, visual acuity (all 4 must match)
- Matching performed by Independent Statistician



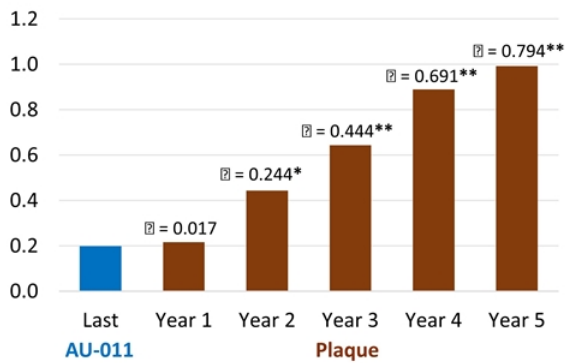
AU-011 has the Potential to Have Long Term Visual Acuity Benefit over Plaque Radiotherapy

*rmCC – retrospective matched case control

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rMCC Results – Statistically Significant Vision Preservation with AU-011 vs Plaque Radiotherapy

Change from Baseline in logMAR[^]



* p < 0.05; ** p < 0.001

[^]logMAR – logarithm of the minimal angle of resolution

Change from Baseline in Vision

Source	Plaque Timepoint	Change in logMAR			
		AU-011	Plaque	Treatment Difference	p-value
AU-011 vs. Plaque	Year 1	0.199	0.216	-0.017	0.8418
	Year 2	0.199	0.443	-0.244	0.0323
	Year 3	0.199	0.643	-0.444	0.0006
	Year 4	0.199	0.890	-0.691	<.0001
	Year 5	0.199	0.992	-0.794	<.0001

- Mixed model repeated measures (MMRM) analysis controlling for matching.
- Comparing last AU-011-101 trial value (average follow up 15.6 months) with plaque timepoints.
- N=43 AU-011 subjects compared to N=150 matched plaque patients.
- Multiple imputation to address missing data.

Statistically Significant Vision Preservation Starting at 2 Years

rMCC Results – Loss of 3 and 6 Lines logMAR Vision

Source	Timepoint	Loss of logMAR of ≥ 0.3		Loss of logMAR of ≥ 0.6	
		%	p-value	%	p-value
AU-011	Last	23.3%	-	14.0%	-
AU-011 vs. Plaque	Year 1	25.7%	0.7627	12.2%	0.7338
	Year 2	42.3%	0.0304	26.0%	0.3571
	Year 3	53.3%	0.0020	35.1%	0.0419
	Year 4	67.1%	<.0001	54.0%	<.0001
	Year 5	73.3%	<.0001	60.1%	<.0001

- Analysis of the proportion of subjects with a loss of logMAR ≥ 0.3 and ≥ 0.6 via Cochran–Mantel–Haenszel test to control for matching.
- Multiple imputation to address missing data.
- Comparing AU-011-101 trial values (average follow up 15.6 months) with Plaque timepoints.

Significantly Higher Proportion of Subjects with Loss ≥ 3 Lines Starting at 2 Years and ≥ 6 Lines Starting at 3 Years with Plaque Radiotherapy vs. AU-011

AU-011 in Combination with Checkpoint Inhibitors
Ruben Huis in t' Veld



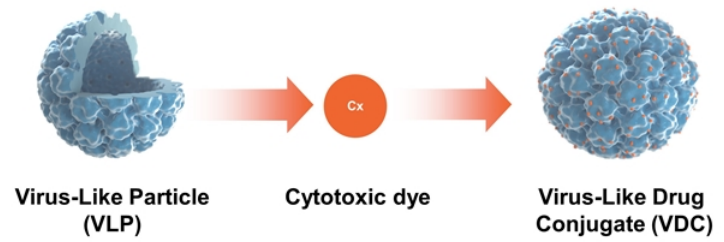
Immune checkpoint inhibition combined with targeted therapy using a novel virus-like drug conjugate

aura

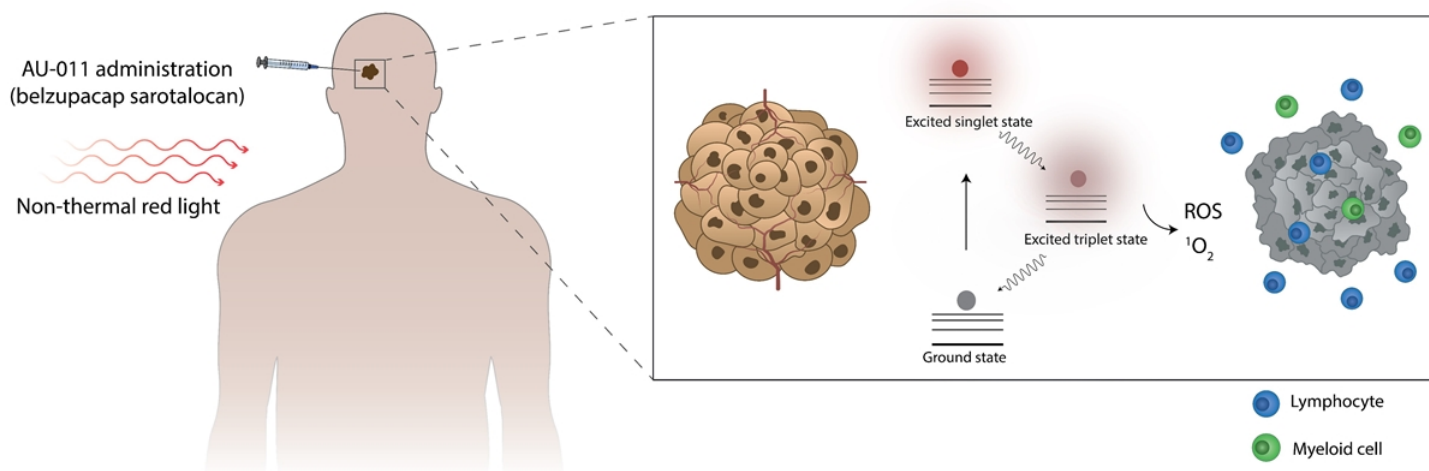
Research sponsored by Health Holland
in collaboration with Aura Biosciences

Health~
Holland

Ruben Huis in 't Veld



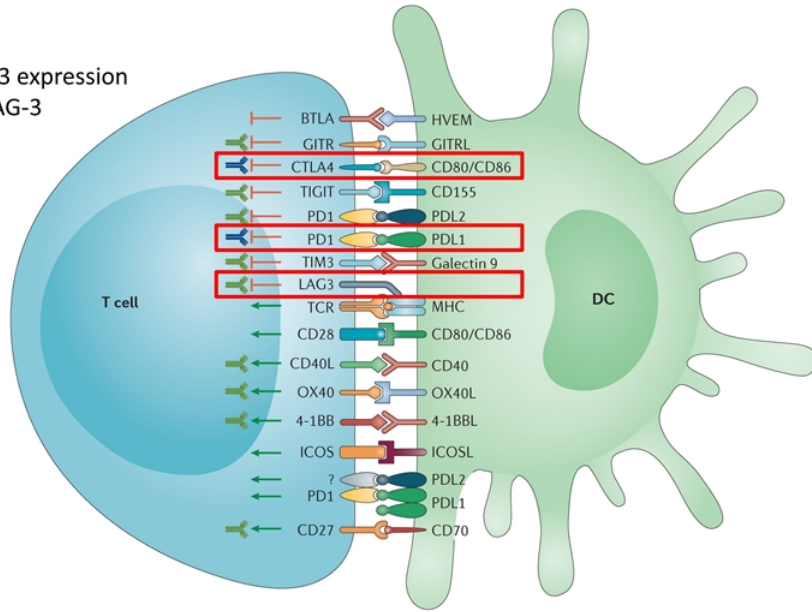
AU-011 is an investigational virus like drug conjugate with a novel mechanism of action



1. Cancer cell directed cytotoxicity
2. Induction of antitumor immune responses

Rationale for combining AU-011 treatment and immune checkpoint inhibition

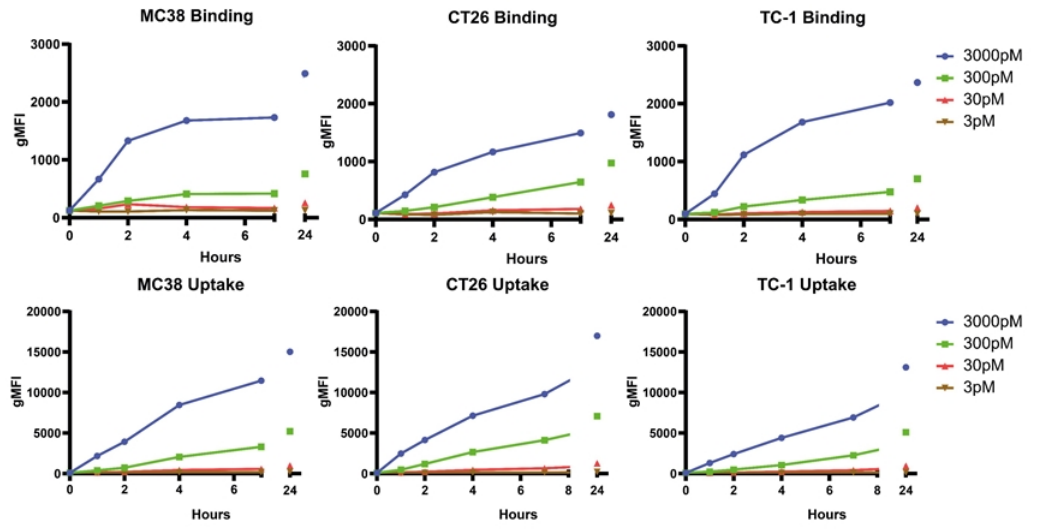
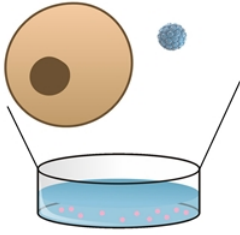
Beyrend et al. (2019):
 PD-L1 blockade induces LAG-3 expression
 → Co-targeting of PD-L1 & LAG-3



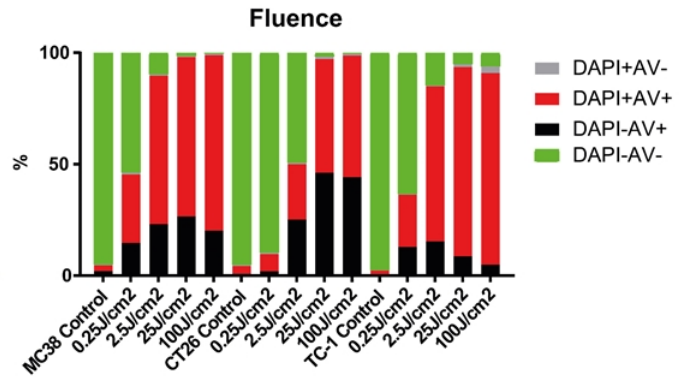
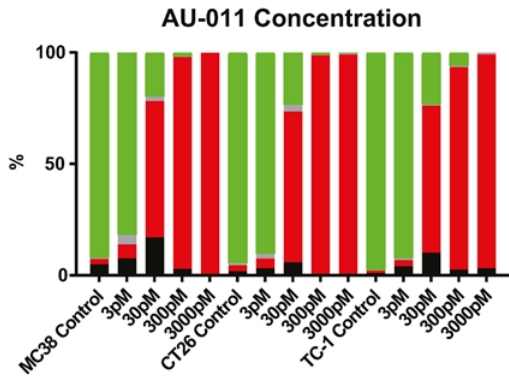
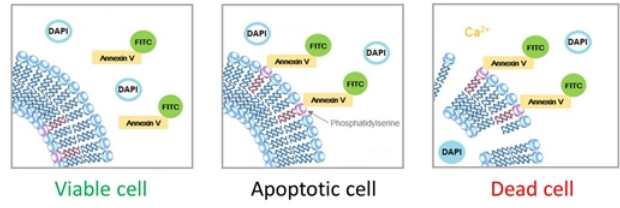
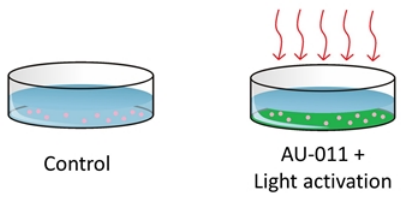
Wykes M. N. & Lewin S. R. Immune checkpoint blockade in infectious diseases. *Nature Reviews Immunology*. 2018;18:91–104

AU-011 has shown binding and uptake in multiple types of tumor cells

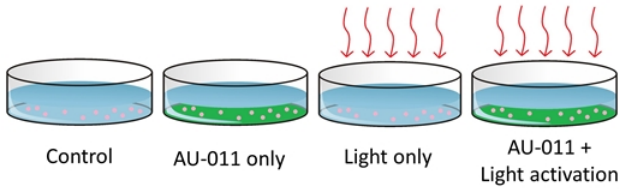
Cancer cells AU-011



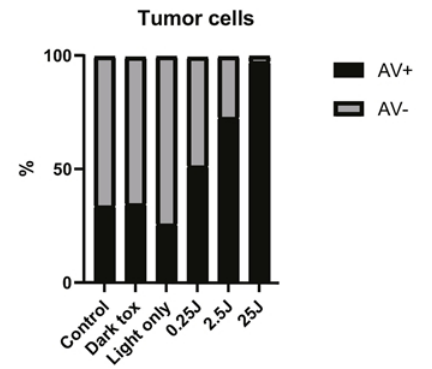
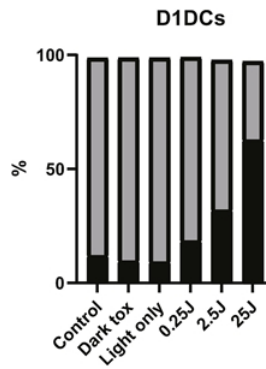
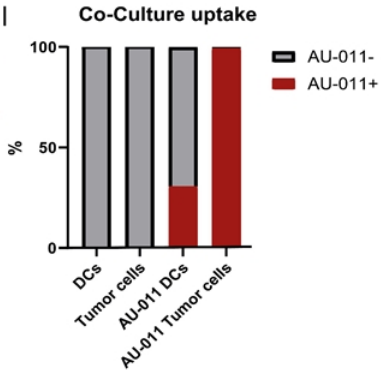
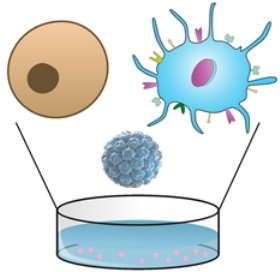
AU-011 + light activation can induce cancer cell death



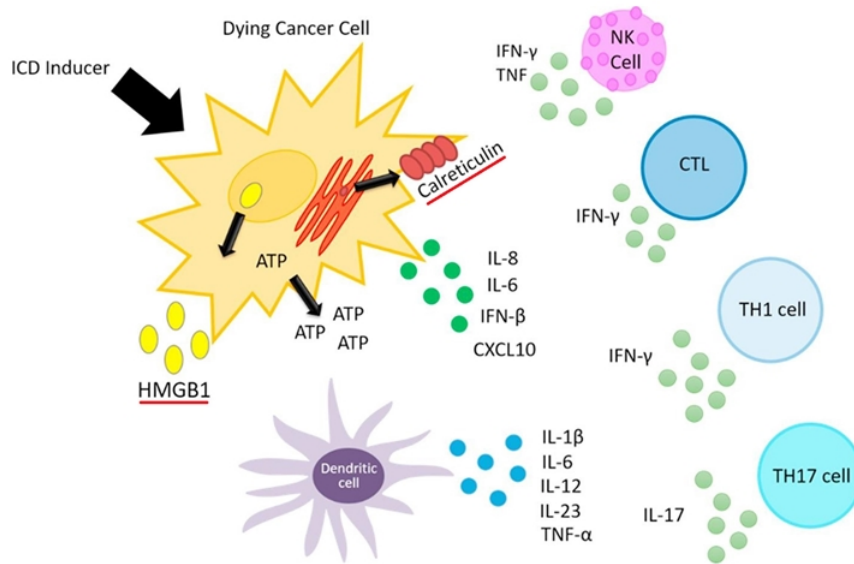
AU-011 treatment can induce cancer cell directed cytotoxicity



Cancer cell Dendritic cell

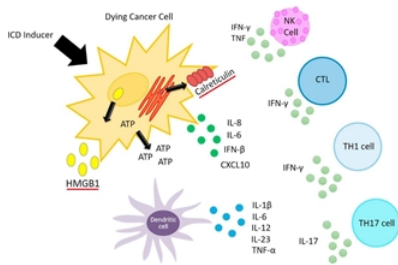


Damage-associated molecular patterns (DAMPs)

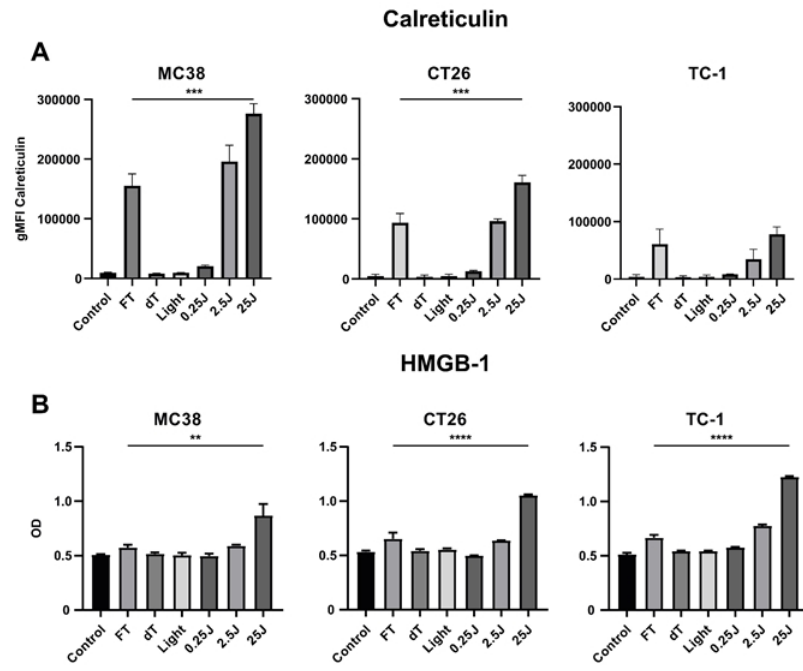


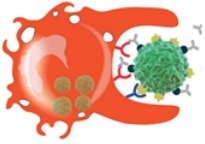
Showalter A. et al. Cytokines in immunogenic cell death: Applications for cancer immunotherapy. *Cytokine*. 2017;97:123-132

Release of DAMPs following AU-011 treatment

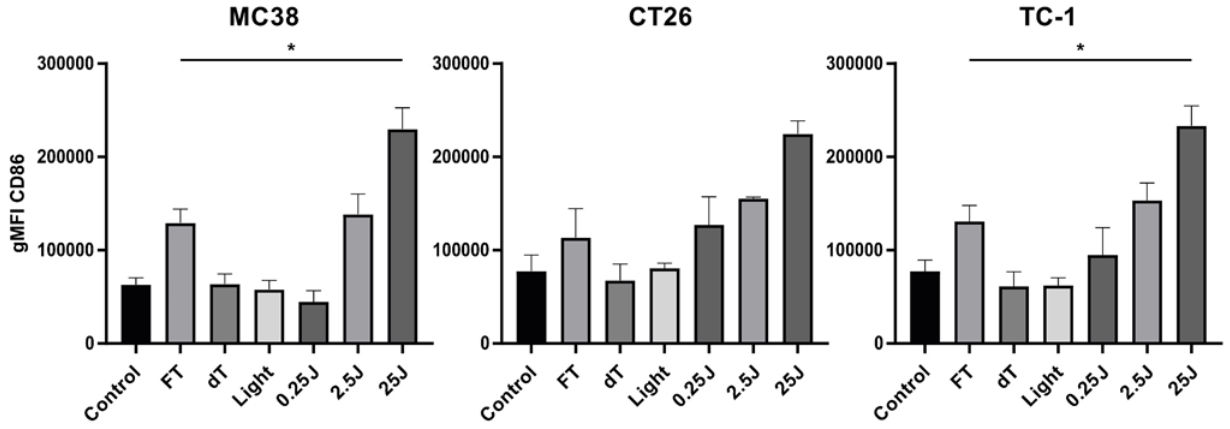


Showalter A. et al. Cytokines in immunogenic cell death: Applications for cancer immunotherapy. *Cytokine*. 2017;97:123-132



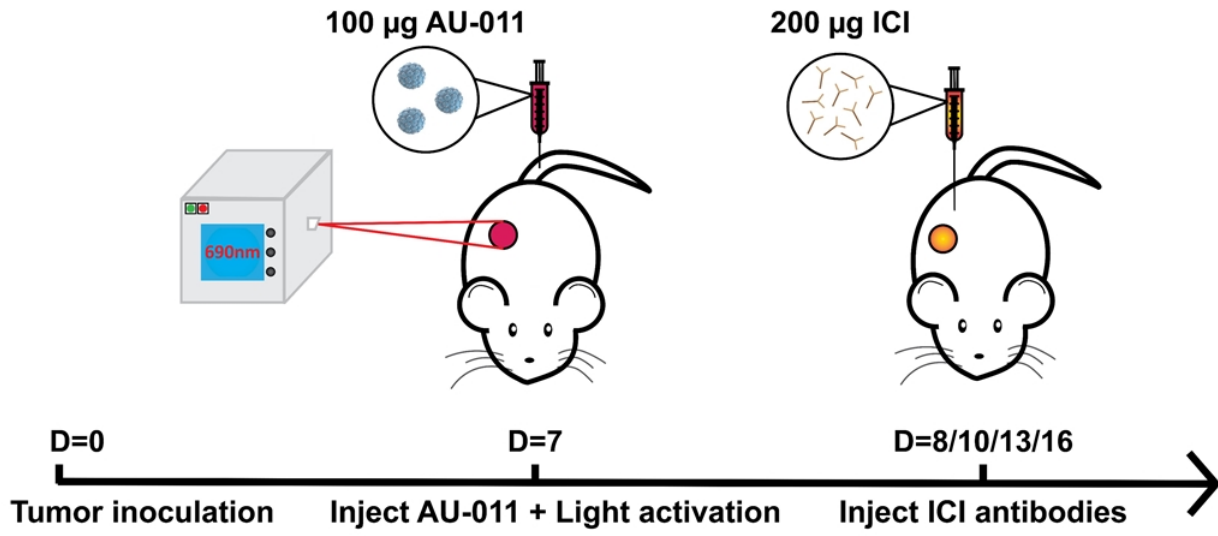


DC Maturation

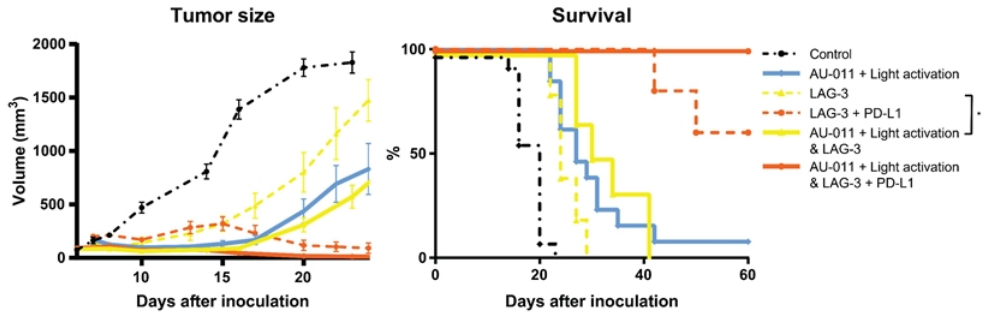
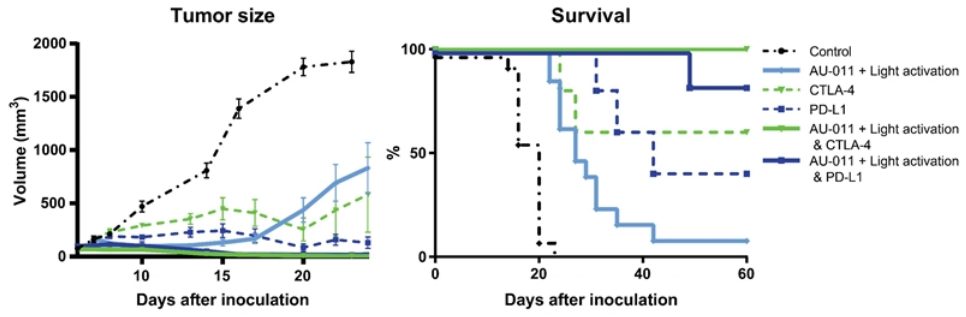


AU-011 + Light activation combined with ICI enhanced treatment response compared to either treatment alone (1 of 2)

400 mW/cm² / 75 J/cm² in 6 pulses

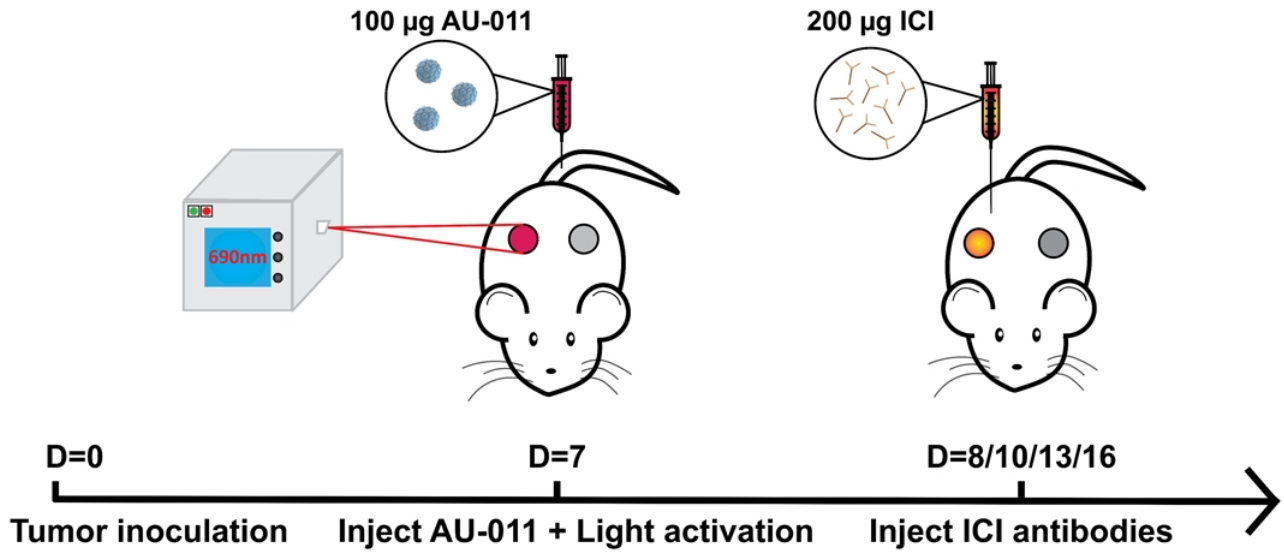


AU-011 + Light activation combined with ICI enhanced treatment response compared to either treatment alone (2 of 2)

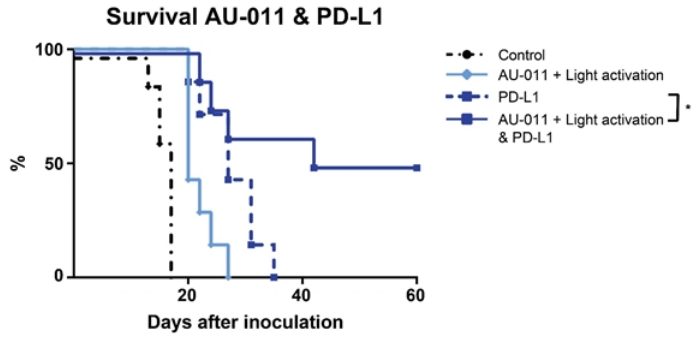
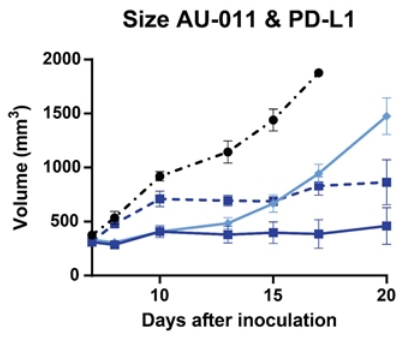
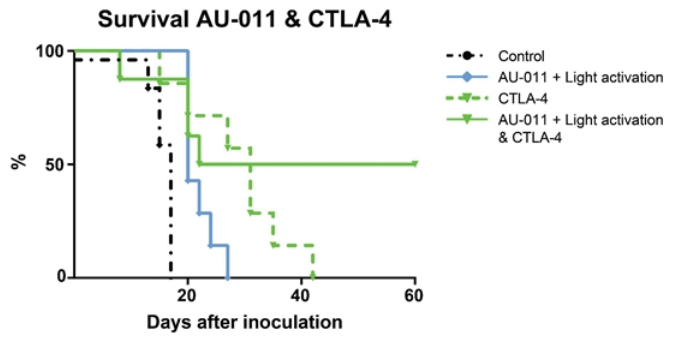
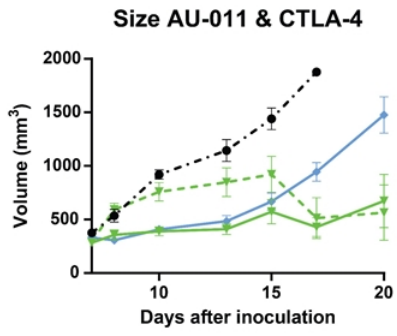


Treatment of primary and distant tumors was enhanced by AU-011 + Light activation with ICI versus either treatment alone (1 of 3)

400 mW/cm² / 75 J/cm² in 6 pulses

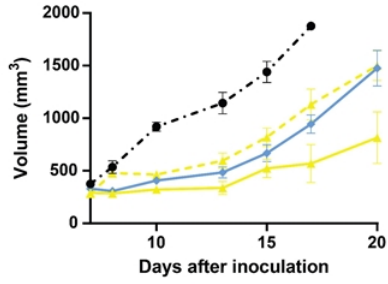


Treatment of primary and distant tumors was enhanced by AU-011 + Light activation with ICI versus either treatment alone (2 of 3)

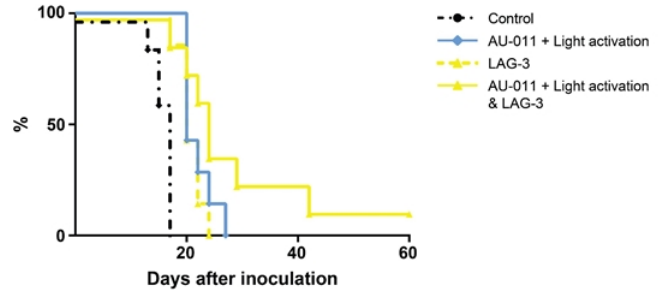


Treatment of primary and distant tumors was enhanced by AU-011 + Light activation with ICI versus either treatment alone (3 of 3)

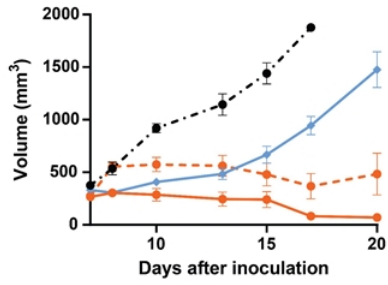
Size AU-011 & LAG-3



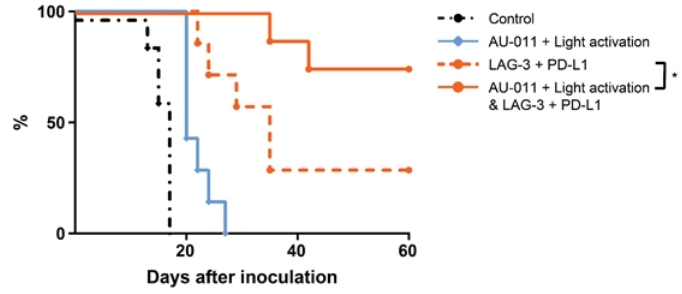
Survival AU-011 & LAG-3



Size AU-011 & LAG-3 + PD-L1



Survival AU-011 & LAG-3 + PD-L1



AU-011 + light activation with ICI enhanced treatment response versus either treatment alone in both primary and distant tumors

		AU-011	CTLA-4	PD-L1	LAG-3	LAG-3 + PD-L1	AU-011 & CTLA-4	AU-011 & PD-L1	AU-011 & LAG-3	AU-011 & LAG-3 + PD-L1
Control	Tumor Volume	****	****	****	****	****	****	****	****	****
	Survival	****	****	****	***	****	****	****	****	****
AU-011	Tumor Volume	-	ns	ns	ns	ns	*	ns	ns	ns
	Survival	-	ns	*	ns	**	***	**	ns	***

Significance of the data presented in figure 5, determined by a one-way ANOVA with Tukey correction for multiple comparisons at day 20 post inoculation for tumor volume and a Mantel-Cox test for survival (* p < 0.05, ** p < 0.01, *** p < 0.001, **** p < 0.0001; n ≥ 8).

AU-011 + Light activation:

- **Induced cancer cell-directed cytotoxicity**
- **Released DAMPs and induced maturation of antigen-presenting cells**
- **Combined with ICI using anti-PD-L1 & anti-LAG-3 antibodies showed potential to induce complete and lasting tumor responses in both primary and distant tumors in murine models**

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Question & Answer



ISOO 2022

Thank you!