Darovasertib Clinical Data Update
September 12, 2022
NASDAQ: **IDYA**

IDEAYA Biosciences

Improving Lives Through Transformative Precision Medicines

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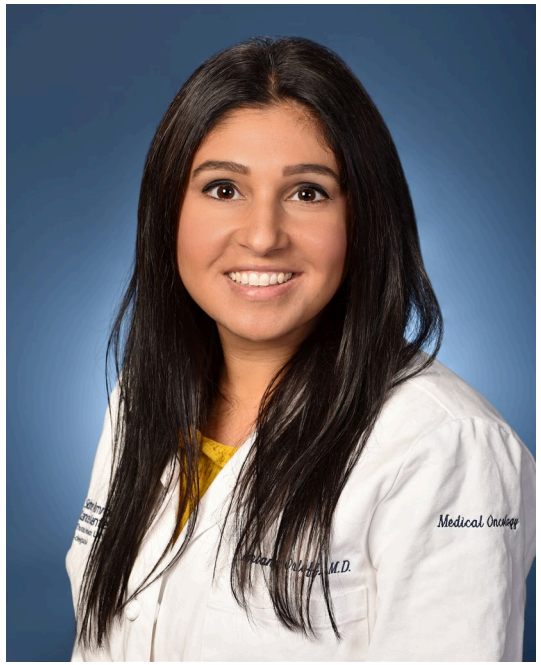
This presentation concerns anticipated products that are under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). It is currently limited by Federal law to investigational use, and no representation is made as to its safety or effectiveness for the purposes for which it is being investigated.

Welcome and Introduction

Yujiro Hata – President and Chief Executive Officer
IDEAYA Biosciences

Welcome to our Participants and Guest Speakers

Darovasertib Clinical Data Update



Marlana Orloff, M.D.
Associate Professor
Sidney Kimmel Cancer Center
Jefferson Health

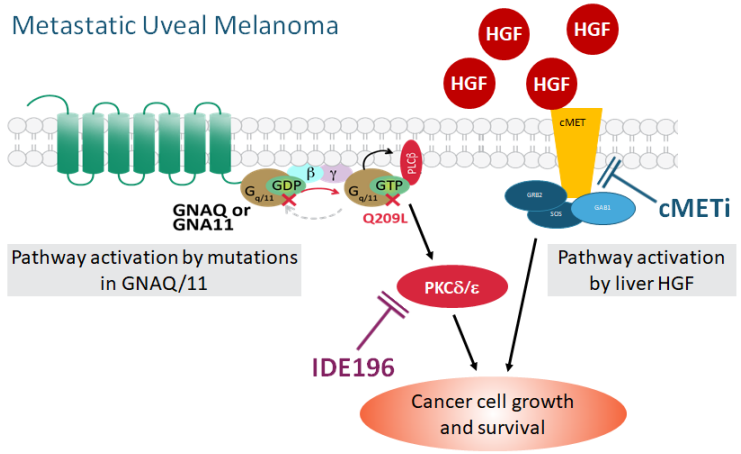
Marcus Butler, M.D.
Princess Margaret Cancer Centre,
and Assistant Professor at the
University of Toronto

Darovasertib + Crizotinib – Phase 2 Synthetic Lethal Combination

Potential First-in-Class and Best-in-Class in MUM, Adjuvant UM and Other GNAQ/11 Tumors

PKC + cMET Synthetic Lethal Discovery

High cMET expression Associated with Metastatic Progression

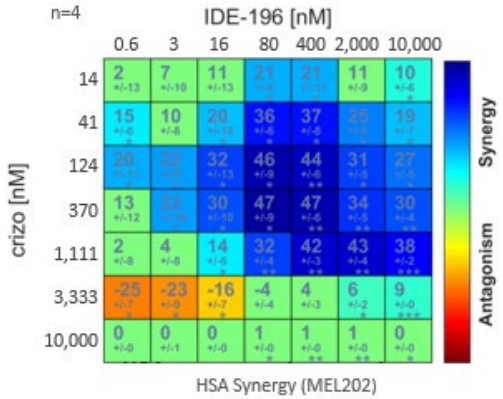


- HGF promotes cancer cell growth and survival
- Translational Research hypothesis: HGF-induced cMET signaling in the liver microenvironment activates an alternative pathway for MUM tumor progression

IDEAYA Darovasertib Investor Day, 2021

Preclinical Synergy

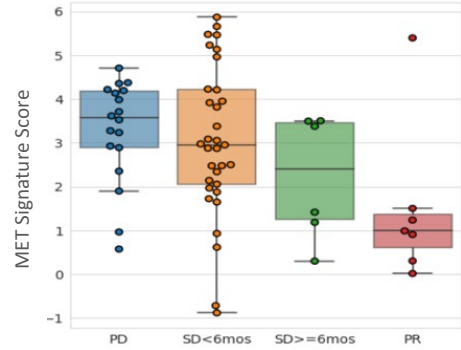
Darovasertib + Crizotinib Synergy in MUM Cells



IDEAYA Data AACR 2021

Clinical Phase 1 Data Association

Darovasertib Ph 1 Association with cMET Activity



Ph 1 Clinical Outcomes

PD=Progressive Disease, SD=Stable Disease, PR=Partial Response

IDEAYA Data

Primary Uveal Melanoma is typically treated with radiation and/or enucleation

Metastatic Uveal Melanoma (MUM) occurs in approximately 50% of patients

MUM presents predominantly as liver metastasis in ~90% of patients

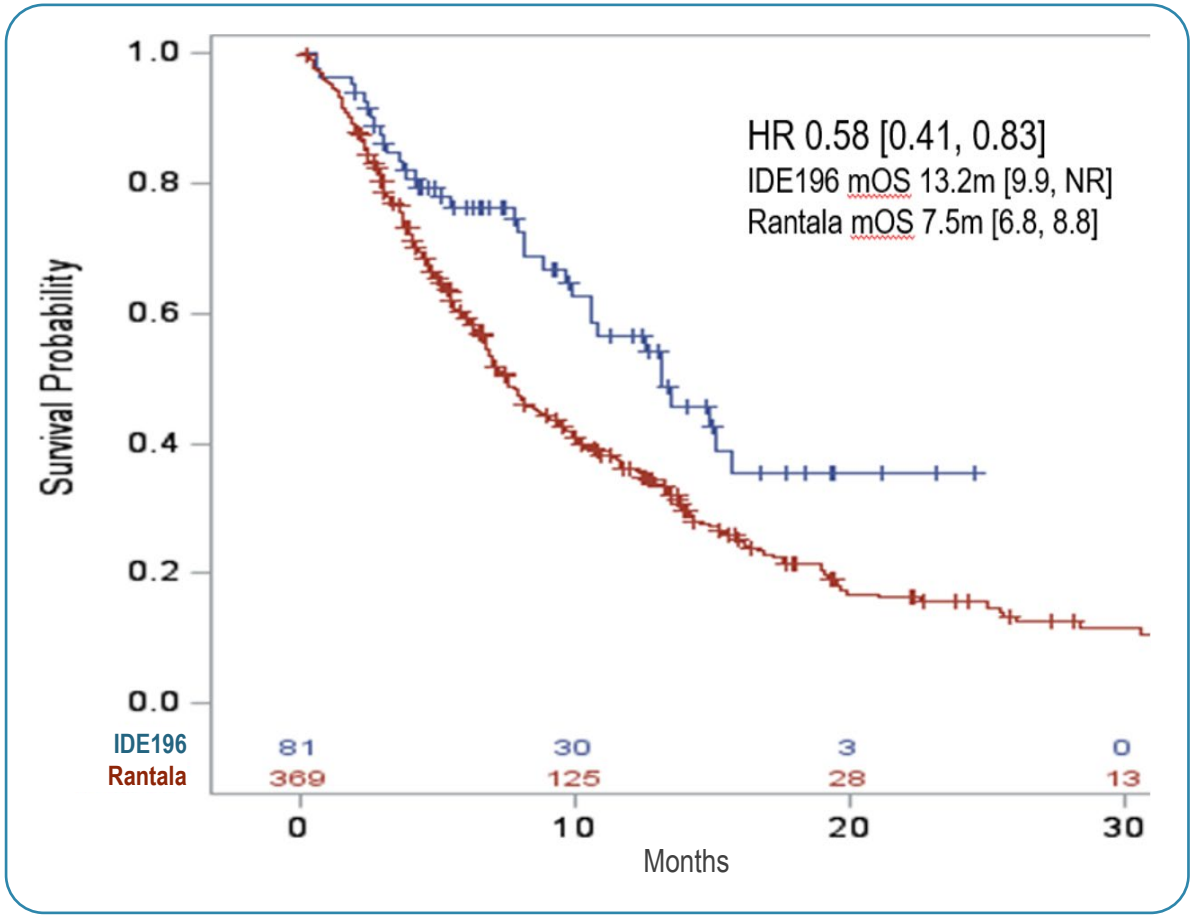
Historical treatment approaches have been ineffective with no approved therapies targeting PKC

Darovasertib advantages vs current MUM therapy: no patient selection, oral, ↑ response rate

Darovasertib Monotherapy Overall Survival in Heavily Pre-Treated MUM

Overall Survival favorable compared to Historical Pretreated Synthetic Control Arm [1,2]

Baseline Characteristics		N=81 (%)
Age	< 65	57 (70.4)
	≥65	24 (29.6)
Sex	F	41 (50.6)
	M	40 (49.4)
ECOG PS	0	61 (75.3)
	1	20 (24.7)
Baseline LDH	Normal	26 (32.1)
	>ULN	54 (66.7)
	Missing	1 (1.2)
Number of Prior Regimens	0	12 (14.8)
	1	30 (37.0)
	≥2	39 (48.1)
Tumor Burden (mm) (Sum of Target Lesions)	Median	82
	Min, Max	11, 301



[1] IDEAYA Data (based on preliminary analysis of unlocked database, including: pooled IDEAYA and Novartis BID monotherapy clinical data as of Apr 13, 2021)
[2] Synthetic Control Arm based on Rantala 2019 (meta-analysis of overall survival of patients with metastatic uveal melanoma over 1980 to 2017 evaluated by treatment modality and lines of treatment)

Daro + Crizo Combo in Comparatively High-Risk, Poor Prognosis Population

Disease Burden Significantly Higher in Both Any-Line and First-Line MUM Population+

Baseline Characteristics		IDE196-001 Study* Darovasertib + Crizotinib		Tebentasfusp Phase 3#
		Any-Line n=37 (%)	First-Line n=8 (%)	n=252 (%)
Age	< 65	20 (54)	3 (38)	64 Median
	≥65	17 (46)	5 (62)	
Sex	F	20 (54)	4 (50)	124 (49)
	M	17 (46)	4 (50)	128 (51)
ECOG PS	0	25 (68)	3 (38)	192 (76)
	1	12 (32)	5 (63)	49 (19)
Baseline LDH	Normal	11 (30)	2 (25)	
	>ULN	**25 (68)**	**6 (75)**	**90 (36)**
	Missing	1 (3)	0	
Largest metastatic lesion	≤3.0 cm	10 (27)	2 (25)	139 (55)
	3.1 to 8.0	**22 (60)**	**4 (50)**	**92 (37)**
	≥ 8.1	**5 (14)**	**2 (25)**	**21 (8)**
Location of metastases	Hepatic only	7 (19)	2 (25)	131 (52)
	Extrahepatic only	1 (3)	0	9 (4)
	Hepatic and Extrahepatic	**29 (78)**	**6 (75)**	**111 (44)**

+ Cross-trial comparisons are not based on head-to-head studies and are presented for informational purposes; no direct comparisons are being made
*IDEAYA Data as of June 26, 2022 (based on preliminary analysis of unlocked database); # N Engl J Med 2021; 385:1196-1206

Darovasertib + Crizotinib Combination Safety Summary

Manageable Side Effect Profile (n=37)

No Drug Related Grade 4/5 AEs

Safety Summary	n=37 (%)
Drug-Related	
AEs	37 (100%)
Grade 3	9 (24%)
Grade 4/5 AEs^	0 (0%) / 0 (0%)
SAEs*	2 (5%)
AEs leading to dose modification	3 (8%)
AEs leading to discontinuation	1 (3%)

Drug-Related AEs with >20% Total Prevalence

Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4/5	Total
Diarrhea	46%	38%	5%	0%	89%
Nausea	35%	38%	0%	0%	73%
Edema peripheral	32%	27%	3%	0%	62%
Vomiting	41%	3%	0%	0%	43%
Dermatitis acneiform	30%	8%	0%	0%	38%
Fatigue	8%	24%	5%	0%	38%
Hypoalbuminemia	14%	24%	0%	0%	38%
Hypotension	19%	8%	0%	0%	27%
Anemia	8%	14%	3%	0%	24%
Dizziness	19%	3%	0%	0%	22%
Dysgeusia	19%	3%	0%	0%	22%
Weight increased	11%	11%	0%	0%	22%

IDEAYA Data as of Jun26, 2022 based on preliminary analysis of unlocked database (n=37)
* The 2 SAEs were syncope events with full resolution and successful restart and continuation of the Daro + Crizo therapy
^ Sponsor observed one Grade 5 SAE after the data cutoff date of June 26, 2022, who had rapid disease progression (tumor involvement of ~40% at pre-screening to >80% at baseline scan) and massive disease burden. The principal investigators reviewed the event and concluded it was most likely due to disease progression, and Sponsor concluded it was most likely due to disease progression and not likely related to study therapies. The event was reported to FDA on August 3, 2022, no follow-up questions have been received as of September 11, 2022, and the trial remains ongoing.

Historical Clinical Trial Data in MUM

Targeted Therapies and Immuno-Oncology Agents+

ESMO 2022: IPI + Nivo Combo in HLA-A2-0201 MUM reports ~6% ORR (2 PRs out of 33 patients)++

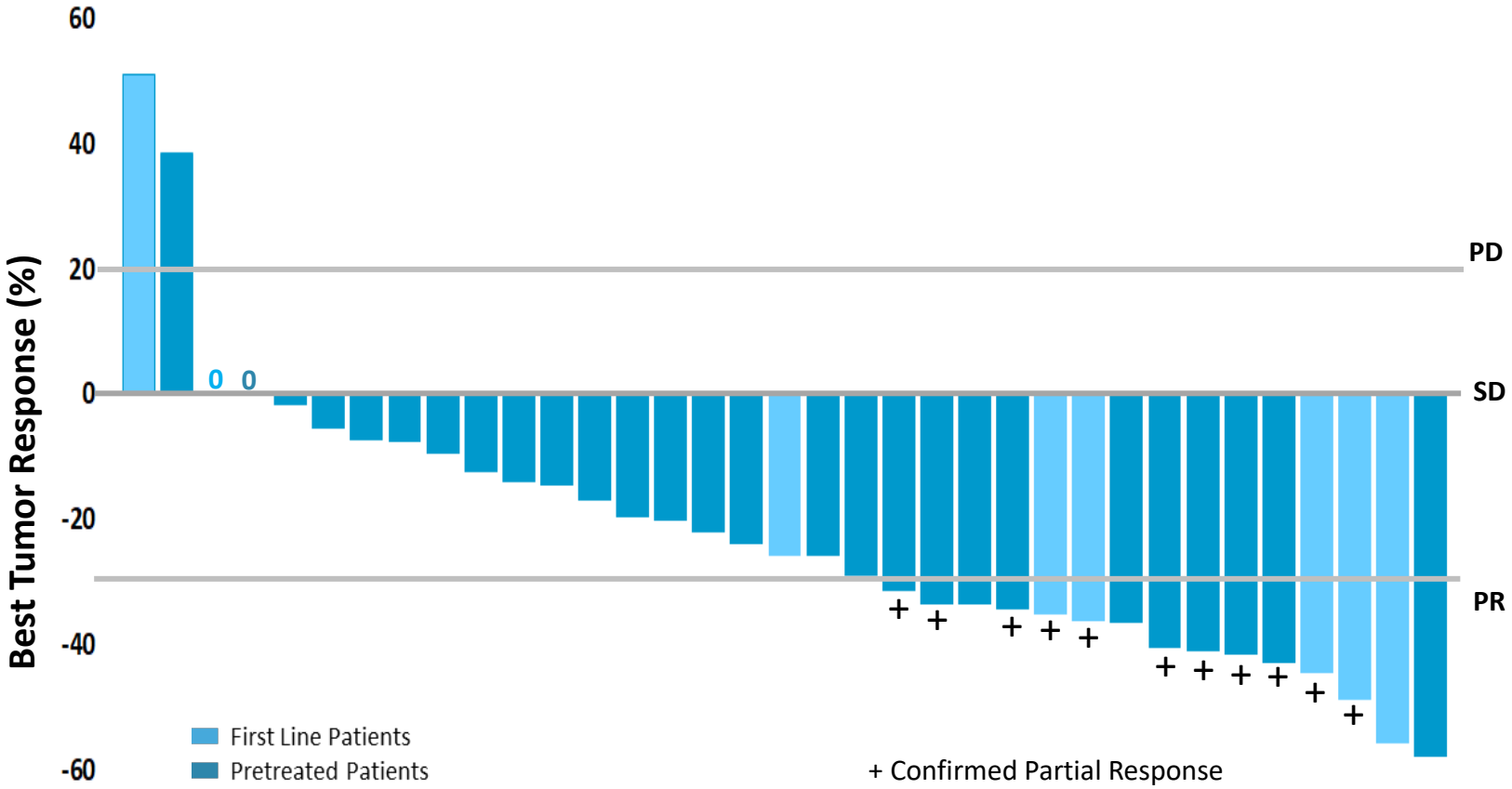
	Darovasertib + Crizotinib	Cabozantinib	Selumetinib + Dacarbazine	Tebentafusp
Target / Mechanism	PKC + cMET	cMET	MEK + Chemotherapy	HLA-A2-0201 Bi-Specific Ab
Study Name	NCT03947385	Alliance A091201^	SUMIT (NCT01974752)	IMCgp100-102
Population	1L/2L/3L+ MUM (n=35 eval)	1L+ MUM (n=31 eval)	1L+ MUM (n=97)	2L+ MUM (n=127)
Patient Selection	N/A (100% of MUM)	N/A (100% of MUM)	N/A (100% of MUM)	HLA-A2-0201 (~40-45% of MUM)
Drug Form	Oral Tablets (BID)	Oral Capsules (QD)	Oral Capsules (BID) plus chemo	IV Infusion (Weekly)
Tolerability (Grade ≥3 Drug-Related AE)	**24%**	**51.6%**	**63% ^^^ (All Cause)**	**46.5%**
% of Pts with Tumor Shrinkage		**23% ^^**	**35%^^**	**44%#**
Overall Response Rate (ORR%, by RECIST 1.1)		**0%**	**3% ^^^**	**4.7%#**
Progression Free Survival (mPFS)		**2 months**	**2.8 months ^^^**	**2.8 months#**

+ Cross-trial comparisons are not based on head-to-head studies and are presented for informational purposes; no direct comparisons are being made
++ ESMO 2022: F. Dimitriou, et.al
* IDEAYA Data: preliminary analysis of unlocked database as of 06/26/2022 by investigator review
# Based on Immunocore reported 2L+ study data (to reflect comparative patient population) and by independent review
^ Randomized Phase II Trial and Tumor Mutational Spectrum Analysis from Cabozantinib versus Chemotherapy in Metastatic Uveal Melanoma (Alliance A091201); Clin Cancer Res 2020;26:804–11
^^ Estimated from Waterfall plot
^^^ Journal of Clinical Oncology, Carjaval, et. al, 2018; 1232-1239

Daro + Crizo Combo Demonstrates Unprecedented ORR% and DCR% in MUM

Any-Line MUM: 31% ORR by RECIST 1.1

Any-Line Waterfall (n=35 Evaluable)



Response Results

Response by RECIST 1.1 Any-Line MUM	Evaluable (N=35)
ORR(11/35)	31%
Tumor Shrinkage (31/35)	89%
>30% Tumor Shrinkage (15/35)	43%
Best Overall Response	
cPR (11/35)	31%
uPR (2/35)	6%
SD (16/35)	46%
DCR (29/35)	83%

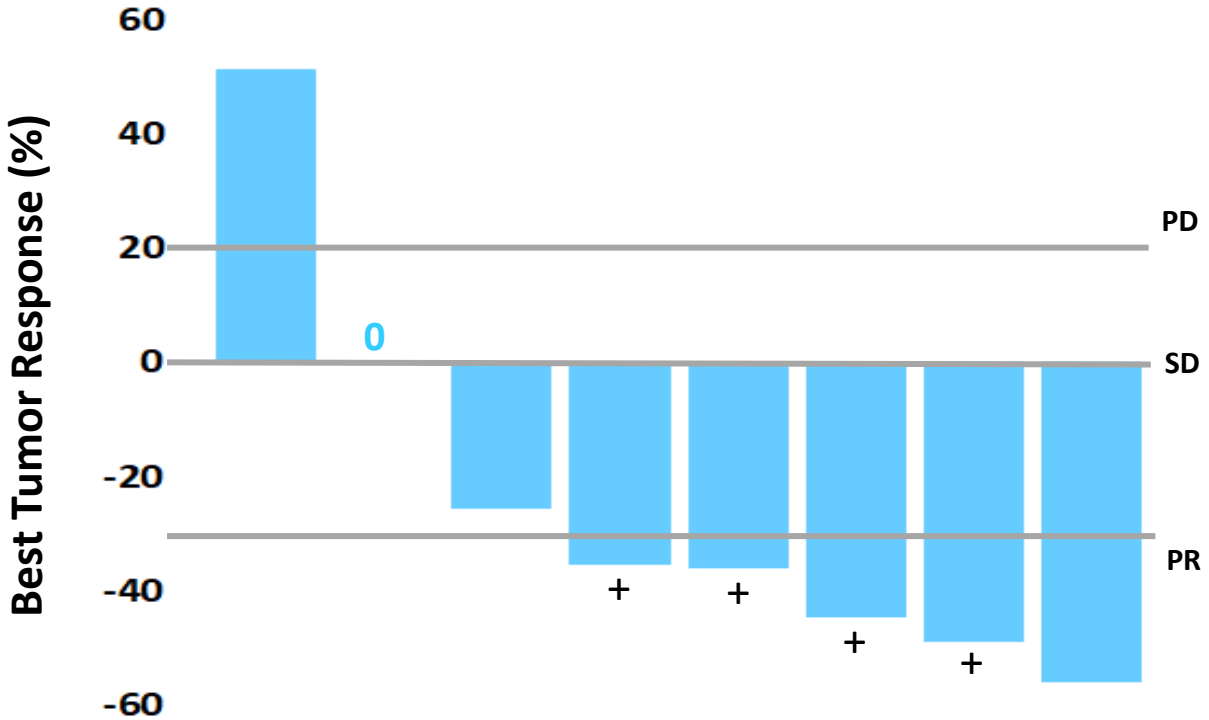
IDEAYA Data: preliminary analysis of unlocked database as of 06/26/2022 by investigator review (n=37); efficacy based on evaluable patients (n=35), including one PR confirmed after cutoff date; two non-evaluable patients, both pretreated, did not progress due to disease: one (1) patient withdrew consent and one (1) patient discontinued early due to fatigue

ORR = Overall Response Rate; DCR = Disease Control Rate; cPR = Confirmed Partial Response; uPR = Unconfirmed Partial Response; SD = Stable Disease

Daro + Crizo Combo Demonstrates Unprecedented ORR% and DCR% in MUM

First-Line MUM: 50% ORR by RECIST 1.1

First-Line Waterfall (n= 8 Evaluable)



+ Confirmed Partial Response

Response Results

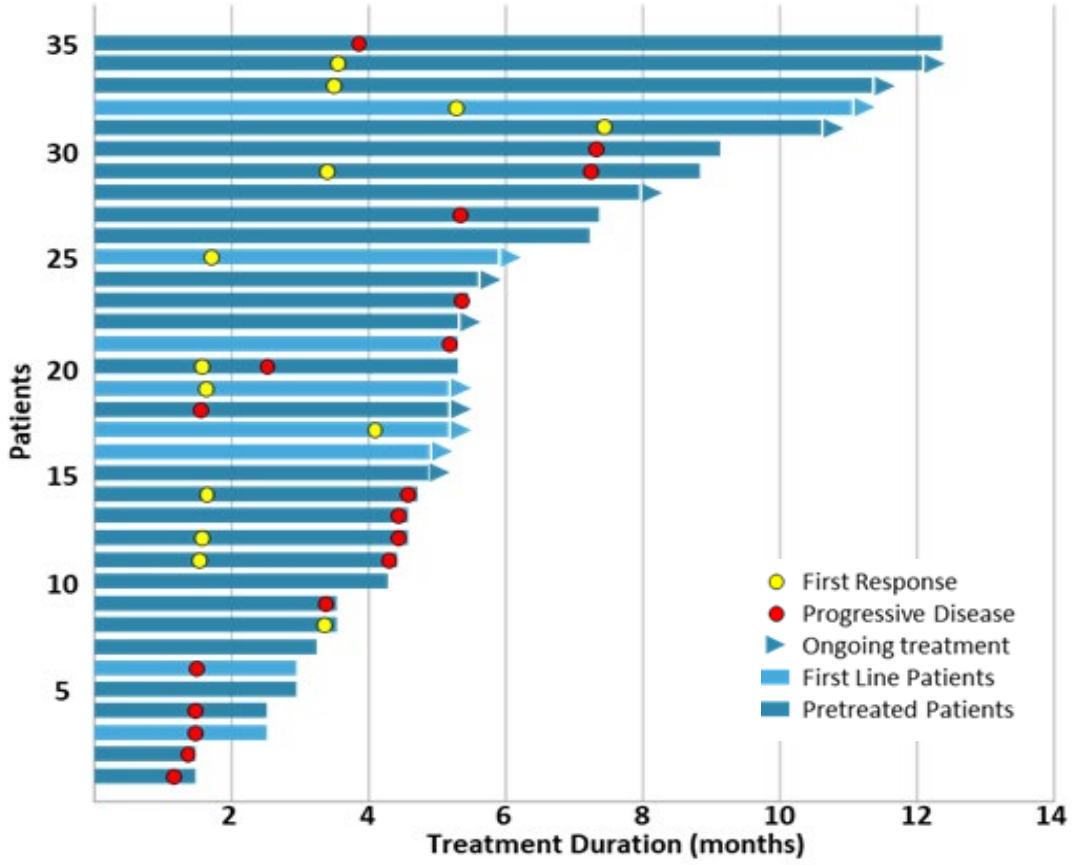
Response by RECIST 1.1 First-Line MUM	Evaluable (N=8)
ORR (4/8)	50%
Tumor Shrinkage (6/8)	75%
>30% Tumor Shrinkage (5/8)	63%
Best Overall Response	
cPR (4/8)*	50%
uPR (0/8)	0%
SD (2/8)	25%
DCR (6/8)	75%

IDEAYA Data: preliminary analysis of unlocked database as of 06/26/2022 by investigator review; efficacy based on evaluable patients (n=8)
ORR = Overall Response Rate; DCR = Disease Control Rate; cPR = Confirmed Partial Response; uPR = Unconfirmed Partial Response; SD = Stable Disease

Darovasertib + Crizotinib Combination Phase 2 Clinical Efficacy

Encouraging mPFS and mDOR in 1L and Any-Line MUM versus historical data in MUM

Darovasertib + Crizozotinib Any-Line MUM (n=35)



Clinical Efficacy Summary in Any-Line and First-Line MUM

Median Study Follow-Up *

- Any-Line: 7.8 months
- First-Line: 6.5 months

Median Duration-of-Response

- Not yet reached in Any-Line or in First-Line
- 7 of 11 cPRs in Any-Line MUM remain in response
- 4 of 4 cPRs in First-Line MUM remain in response

Median Progression Free Survival ^

- Any-Line: ~5 months
- First-Line: Not yet reached and >5 months

IDEAYA Data: preliminary analysis of unlocked database as of 06/26/2022 by investigator review

* Median Study Follow-up: Cycle 1 Day 1 to data cut-off date (n=37)

^ mPFS Analysis: median assessment estimated, based on efficacy-evaluable patients (n=35)

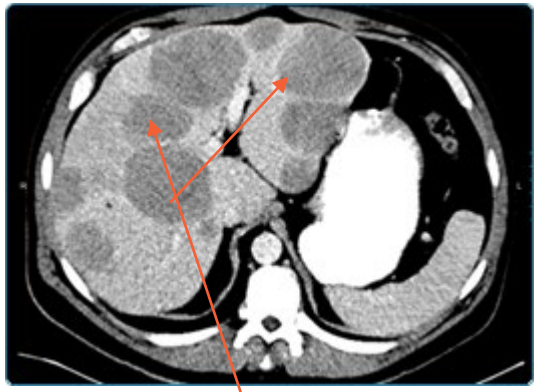
Darovasertib + Crizotinib Combination Efficacy in First-Line MUM

Examples of cPRs with Significant Tumor Shrinkage in First-Line MUM Patients

First-Line MUM Patient

- 40+ year old patient with ongoing response at 12 months
- Diffuse disease in liver and pelvis with elevated LDH of 800 that normalized within one month
- Large tumors (SLD = 210 mm) reduced by 49%

Baseline



Many lesions distorting and replacing the liver

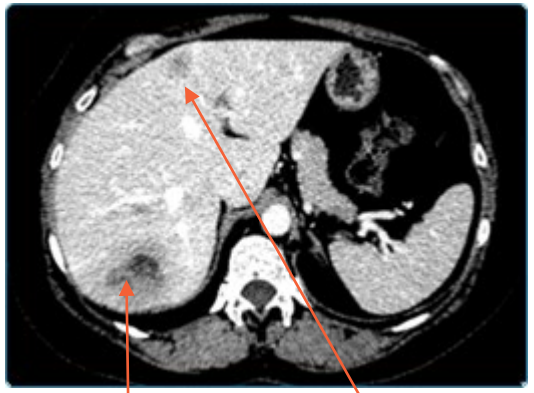
12 months

Marked improvement across all lesions

First-Line MUM Patient

- 50+ year old patient with ongoing response at 5 months
- Diffuse disease in liver & lymph nodes with elevated LDH
- Many liver lesions with target lesions reduced by 53%
- Intact orbital lesion reduced by 67%

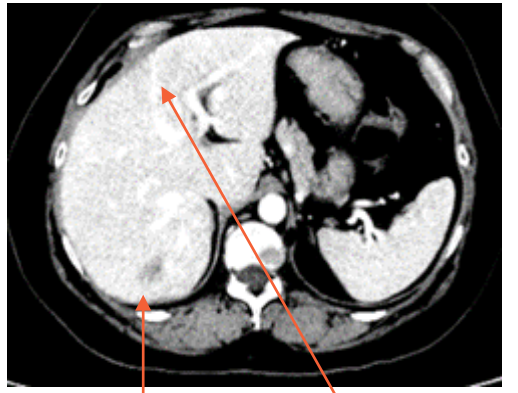
Baseline



Large necrotic lesion

Lesion

5 months



Markedly improved

Lesion Not Visible

IDEAYA Data as of 06/26/2022 (based on preliminary analysis of unlocked database); tumor lesion reductions by investigator review

Darovasertib + Crizotinib Synthetic Lethality Combination Therapy

Differentiated Clinical Efficacy in MUM+

ESMO 2022: IPI + Nivo Combo in HLA-A2-0201 MUM reports ~6% ORR (2 PRs out of 33 patients)++

	Darovasertib + Crizotinib	Cabozantinib	Selumetinib + Dacarbazine	Tebentafusp
Target / Mechanism	PKC + cMET	cMET	MEK + Chemotherapy	HLA-A2-0201 Bi-Specific Ab
Study Name	NCT03947385	Alliance A091201^	SUMIT (NCT01974752)	IMCgp100-102
Population	1L/2L/3L+ MUM (n=35 eval)	1L+ MUM (n=31 eval)	1L+ MUM (n=97)	2L+ MUM (n=127)
Patient Selection	N/A (100% of MUM)	N/A (100% of MUM)	N/A (100% of MUM)	HLA-A2-0201 (~40-45% of MUM)
Drug Form	Oral Tablets (BID)	Oral Capsules (QD)	Oral Capsules (BID) plus chemo	IV Infusion (Weekly)
Tolerability (Grade ≥3 Drug-Related AE)	**24%**	**51.6%**	**63% ^^^ (All Cause)**	**46.5%**
% of Pts with Tumor Shrinkage	**89%***	**23% ^^**	**35%^^**	**44%#**
Overall Response Rate (ORR%, by RECIST 1.1)	**All-Line = 31% / First-Line = 50%* (confirmed PRs only)**	**0%**	**3% ^^^**	**4.7%#**
Progression Free Survival (mPFS)	**All-Line: ~5 months / First-Line: >5 months**	**2 months**	**2.8 months ^^^**	**2.8 months#**

+ Cross-trial comparisons are not based on head-to-head studies and are presented for informational purposes; no direct comparisons are being made

++ ESMO 2022: F. Dimitriou, et.al

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^^ Estimated from Waterfall plot

^^^ Journal of Clinical Oncology, Carjaval, et. al, 2018; 1232-1239

IDEAYA BIOSCIENCES

Darovasertib + Crizotinib Clinical Development Plan in First-Line MUM

Targeting Potential Registration Enabling Trial Initiation in Q1 2023[1]

Key Considerations

- 1st Line vs All-Line
  - Unmet Need
  - Better Assessment
  - FDA Project Frontrunner
- HLA-A*02:01 Serotype
  - Negative vs. All
  - Negative = No FDA Approved Therapies & 55-60% of Patients
  - Off-Label Use / Label Expansion (all data including pretreated pts)
- Single-Arm vs Randomized
- Surrogate Endpoint
  - Single Arm – ORR with DOR
  - Randomized – PFS
- Strategic Implications
  - Time / Probability for Approval
  - Commercial Opportunity

Single-Arm Phase 2

Single-Arm Phase 2 Trial (Expand Ongoing) in 1L Patients

Darovasertib + Crizotinib

Phase 2 Endpoint – ORR, Target ≥ 20%
Phase 2 Data → Accelerated Approval

Randomized Phase 3 Confirmatory Study in 1L Patients

R 2:1
- Darovasertib + Crizotinib
- Investigator Choice

Phase 3 Endpoints – PFS and OS
PFS Target ≥ 5-6 months

Randomized Integrated Phase 2/3

Randomized Integrated Phase 2/3 Trial in 1L Patients

R 2:1
- Darovasertib + Crizotinib
- Investigator Choice

Phase 2 Endpoint – ORR, Target ≥ 20%
Phase 2 Data → Accelerated Approval

Expand within same Study Protocol → Phase 3 Confirmation

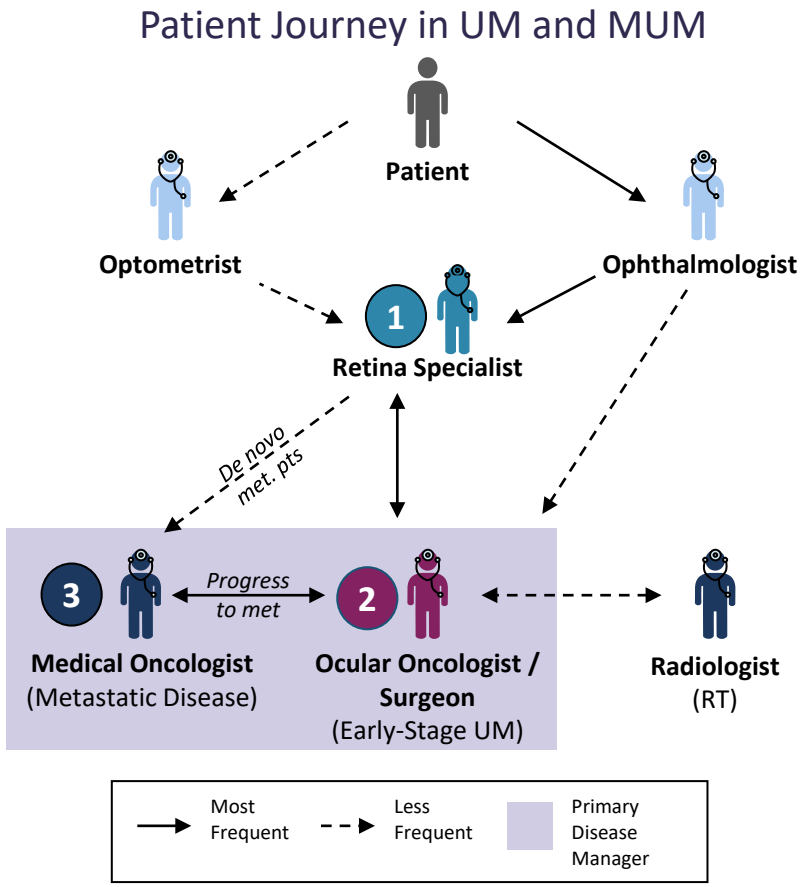
Phase 3 Endpoints – PFS, OS
PFS Target ≥ 5-6 months

[1] Potential scenarios for accelerated approval, including Single Arm Phase 2, Randomized Phase 2 (with Randomized Ph 3 Confirmatory Study, not shown), and Integrated Ph 2/3, subject to clinical investigator and regulatory guidance

Darovasertib Use in (Neo)Adjuvant Uveal Melanoma

Preliminary Clinical Proof-of-Concept Supports Evaluation of UM Expansion Opportunity

Observed tumor shrinkage of primary ocular lesions in 5 of 5 (100%) UM / MUM patients on Monotherapy or +Crizo Combination



1 Initial Diagnosis

- High concentration of patients diagnosed / managed across specialized centers
- Retina Specialists refer patients to Ocular Oncologists / Surgeons or Medical Oncologists

2 Early-Stage Testing, Treatment and Monitoring (UM)

- Ocular Oncologists / Surgeons treat early-stage primary Uveal Melanoma (UM)
- No FDA-approved (neo)adjuvant therapies
- Expansion opportunity for Darovasertib; potential for novel, near-term clinical endpoints

3 Metastatic Treatment (MUM)

- Medical Oncologists treat Metastatic Uveal Melanoma (MUM)
- Competitor product only approved for HLA-A*02:01-positive patients (~40-45% MUM)
- Darovasertib is a differentiated oral therapeutic with enhanced efficacy which enables attractive value proposition across stakeholders – Patients, Medical Oncologists, Payors

IDEAYA / ClearView Analysis; RT = Radiation Therapy

Preliminary Clinical Proof-of-Concept for Darovasertib in (Neo)Adjuvant UM

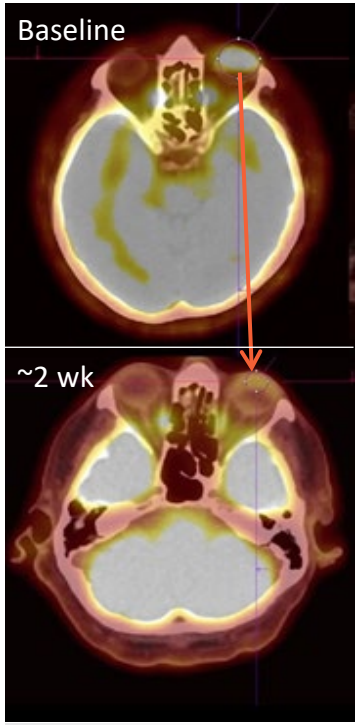
Observed Partial Responses in the Uvea of MUM Patients having Intact Primary Tumor

Darovasertib Monotherapy in MUM with Intact Primary

Observed Partial Response in Uvea Lesion

- 70+ year old pt
- Metastatic disease
- Intact 1^{o} lesion
- Daro monotherapy
- ~74% reduction in ocular lesion at ~ 2 weeks on Darovasertib by PET *
- Improvement in visual symptoms in affected eye
- 32% tumor reduction in target lesions (PR) at Month 2 scan by RECIST 1.1

Patient Remained on Treatment ~ 7 mo



~74% Tumor Reduction*

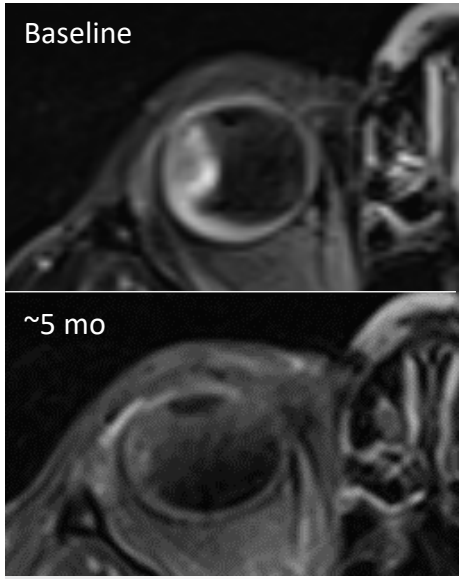
Images (PET) courtesy of Matthew Carlino, MBBS, FRACP, PhD
IDEAYA Data; * PET Standard Uptake Value (SUV)

Daro + Crizo Combination Therapy in MUM with Intact Primary

Observed Partial Response in Uvea Lesion

- 50+ year old pt
- First-Line MUM
- Intact 1^{o} lesion
- Daro + Crizo
- ~67% reduction in ocular lesion
- Visual symptoms improved with treatment
- Confirmed PR

Patient Remains on Treatment at ~ 5 mo ^



~67% Tumor Reduction

Images (MRI) courtesy of Marcus Butler, MD
IDEAYA Data ; confirmed PR by RECIST 1.1, ^ Patient remains on treatment as of August 19, 2022

Preliminary Clinical Proof-of-Concept for Darovasertib in (Neo)Adjuvant UM

~20% Tumor Reduction at 27 days in 1st Neoadjuvant Pt Treated with Daro Monotherapy

(Neo)Adjuvant Monotherapy IST [1]

Primary Uveal Melanoma Patients
with Planned Enucleation Surgery

↓

Darovasertib Monotherapy
Up to 28 Days Prior to Surgery

↓

Enucleation Surgery

↓

Adjuvant Therapy

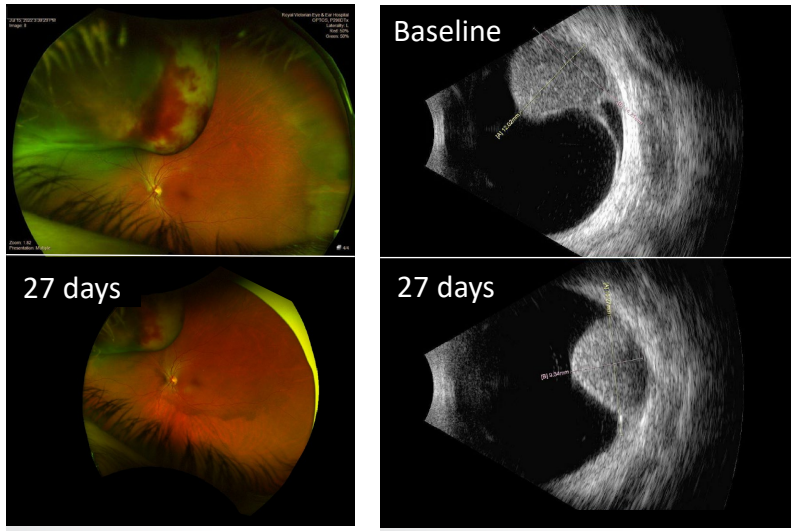
↓

Follow-Up

[1] Investigator Sponsored Trial (IST) NCT05187884
Neoadjuvant/Adjuvant Trial of Darovasertib in Ocular Melanoma (NADOM)

Darovasertib Neoadjuvant UM

Darovasertib Monotherapy Patient Prior to Enucleation



Decreased Vasculature

~20% Tumor Reduction

Observed ~20% Tumor Reduction in Primary Uvea
at 1st Scan (with 27 days of treatment) ^

Images (Ultrasound) courtesy of Ocular Oncology Unit of the Royal Victorian Eye and Ear Hospital
IST Data; tumor reduction by RECIST 1.1; patient remains on treatment at ~ 1 mo as of August 19, 2022

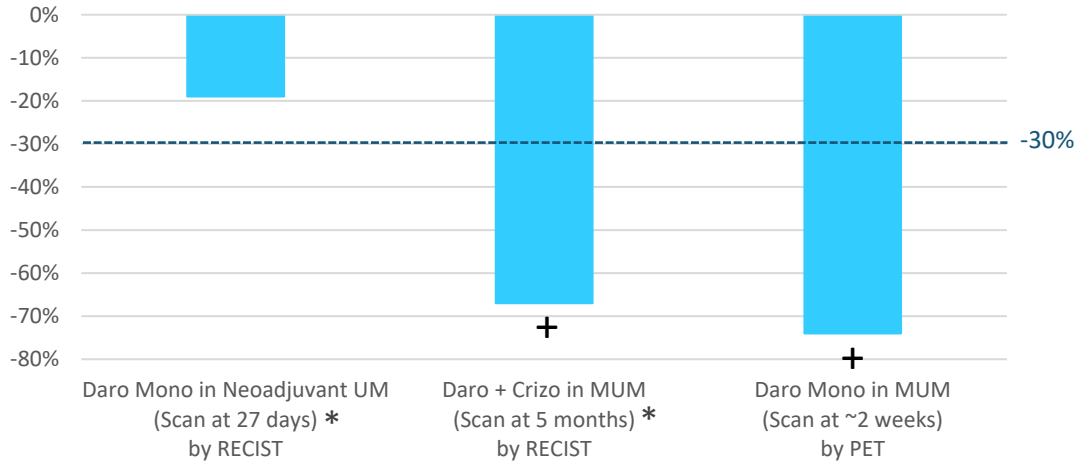
IDEAYA BIOSCIENCES

Darovasertib Monotherapy in (Neo)Adjuvant Uveal Melanoma

Potential Trial Design, Pending Clinical Investigator and Regulatory Guidance

Preliminary (Neo)Adjuvant UM Clinical PoC

Reduction in Uveal Melanoma Lesions Treated by Daro Monotherapy or Daro + Crizo Combination in UM or MUM Patients



\+ Patient observed improvement in visual symptoms

- Preliminary clinical proof-of-concept for potential use in (neo)adjuvant UM with **observed responses in primary orbital lesions**
- **Tumor shrinkage observed in 5 of 5 (100%) primary UM lesions**, including three patients (data shown) + two additional patients after data cut-off date^
- Evaluating **novel near-term clinical endpoints** such as vision preservation and organ preservation (avoid enucleation)

Phase 2 Study Design for (Neo)Adujvant UM [1]

Primary Uveal Melanoma Patients without Metastases and Ineligible for Radiation

↓

Darovasertib Monotherapy Until Maximum Benefit

↓

Radiation

Potential Clinical Endpoints: Vision / Organ Preservation

↓

Follow-up

Targeting Phase 2 Clinical Trial to Evaluate Darovasertib in (Neo)Adjuvant UM in Q4 2022

[1] Preliminary Phase 2 study plan, pending clinical investigator and regulatory guidance; potential to evaluate darovasertib as monotherapy and potentially in combination with crizotinib

* Patient remains on treatment as of August 19, 2022 data cutoff; based on preliminary analysis of unlocked database

^ Additional patients (not shown) based on preliminary observation of tumor reductions in uvea lesion of (i) a Daro + Crizo MUM patient with an intact primary lesion, and (ii) a Darovasertib monotherapy UM patient enrolled in the (neo)adjuvant IST (NADOM) study

IDEAYA BIOSCIENCES

Uveal Melanoma and MUM Treatment Paradigm

US/EU Annual Incidence and Prevalence

Darovasertib Monotherapy – Neoadjuvant UM

Clinical Approach: administer darovasertib as a neoadjuvant therapy to reduce ocular tumor size

- → Enable primary interventional procedures which preserve the eye and/or eye function
- → Estimates of ~8,500-11,000 addressable patients for Choroidal Melanoma subset of UM^
- → Targeting IDEAYA-Sponsored Trial Q4 2022

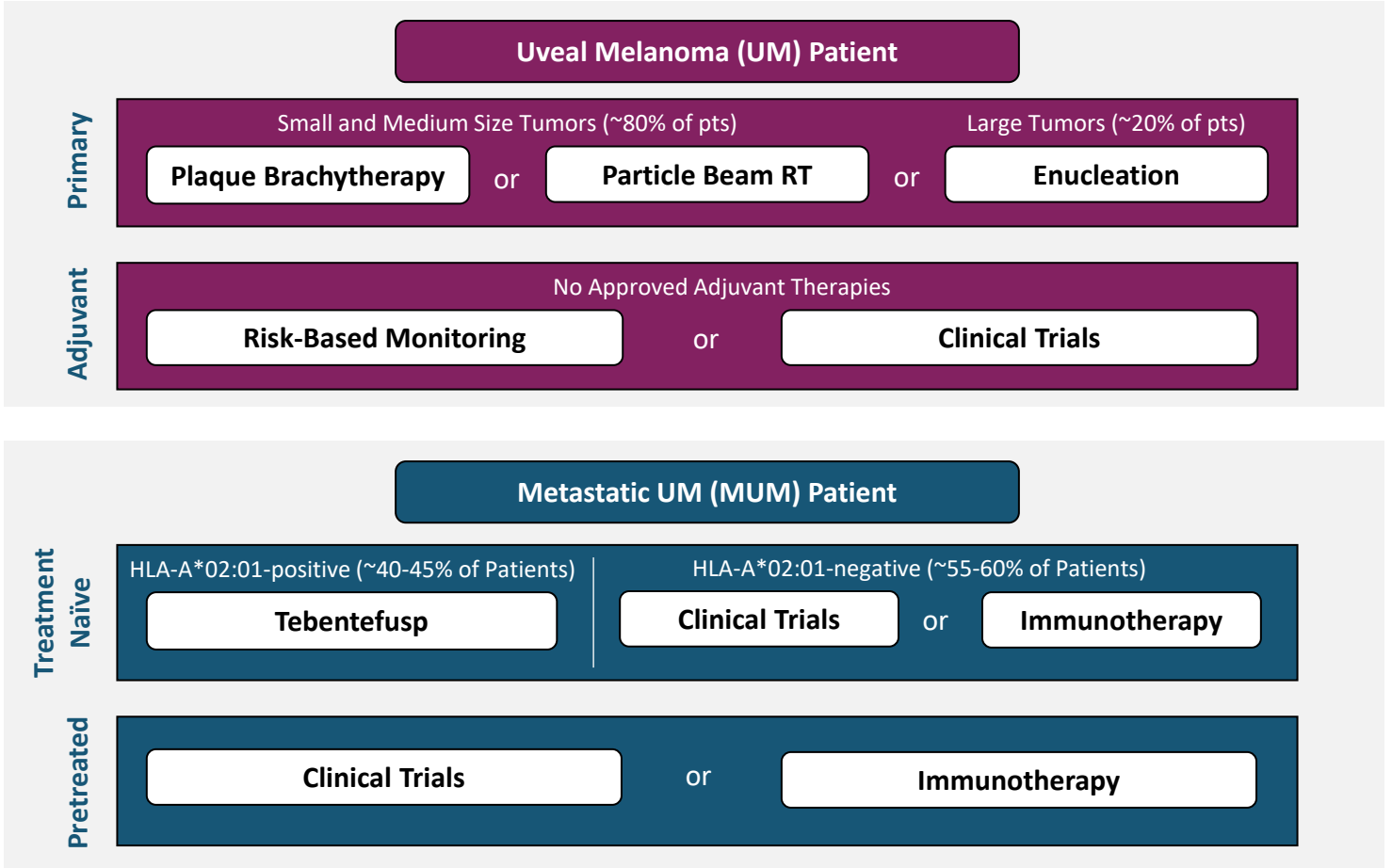
US/EU28 UM Annual Incidence	US/EU28 UM Total Prevalence
~8.7 K	~99.7 K

Darovasertib + Crizotinib – MUM

Clinical Approach: Daro+Crizo as synthetic lethality combination with enhanced clinical efficacy

- → Targeting Potential Registrational Trial Q1 2023

US/EU28 MUM Annual Incidence	US/EU28 MUM Total Prevalence
~4.5 K	~14.4 K



Total Annual Incidence of over 13,000 Patients

Orphan Drug Designation (ODD) for Darovasertib in UM and MUM

IDEAYA / ClearView Analysis; RT: Radiation Therapy; UM: Uveal Melanoma

^ Estimated addressable patient population for US / EU (Sources: Evercore, Cowen), with projected peak revenues for Aura Biosciences AU-011 in Choroidal Melanoma ranging from $600M to ~$1B (Sources: Evercore, Cowen, SVB Leerink)

Closing Remarks – Darovasertib Clinical Data Update

Darovasertib + Crizotinib Clinical Efficacy & AE Summary in MUM [1]

- 31 of 35 (89%) evaluable Any-Line MUM patients observed tumor shrinkage
- 50% ORR (4/8 cPRs) in First-Line MUM and 31% ORR (11/35 cPRs) in Any-Line MUM
- mPFS not yet reached and >5 months in First-Line MUM; mPFS ~5 months in Any-Line MUM
- Manageable safety profile with low rates of both discontinuations and high-grade adverse events
- Historical MUM clinical efficacy (high unmet need): ~0 to 5% ORR and mPFS from ~2 to 3 months

Neo-Adjuvant / Adjuvant UM Opportunity

- Preliminary clinical proof-of-concept for potential use in (neo)adjuvant UM with PRs in uvea lesions
- Initial clinical evaluation in (neo)adjuvant UM will be Darovasertib monotherapy
- High unmet need with potentially addressable annual patient incidence of US / EU28 ~8,700 patients

Next Target Program Milestones

- Targeting initiation of Darovasertib monotherapy (neo)adjuvant UM company-sponsored trial in Q4 2022
- Targeting initiation of potential registration-enabling trial in MUM in Q1 2023

[1] IDEAYA Data: based on preliminary analysis of unlocked database as of 06/26/2022 by investigator review

Analyst Q&A

Yujiro Hata – President and Chief Executive Officer
IDEAYA Biosciences