

# New Medications in Solid Tumors

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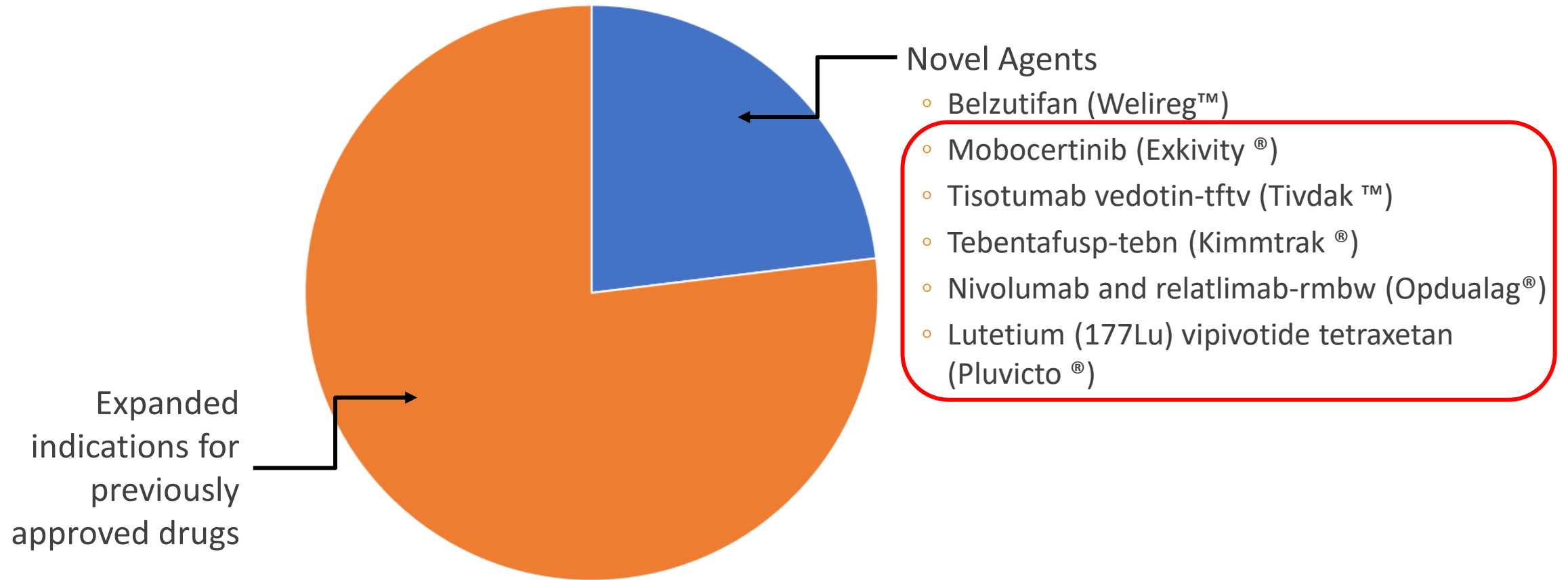
# Disclosures

- I have nothing to disclose.

# Learning Objectives

- Review novel agents approved for the treatment of solid tumors in the last year and describe the following for each drug:
  - Dosing/administration
  - Mechanism of action
  - PK/PD and drug interactions
  - Boxed warnings, warnings/precautions, and common adverse reactions
- Summarize clinical trial data that led to FDA approval of these novel agents.
- Review the treatment paradigm for relevant disease states and highlight the place in therapy for each drug.
- Discuss the significance of each drug approval and future directions for these medications.

# FDA Drug Approvals for Solid Tumors



# Mobocertinib

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# Mobocertinib (Exkivity®)



## Mobocertinib

Approval Date	9/15/2021
Indication	Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion ( <i>EGFR</i> ex20ins) mutations whose disease has progressed on or after platinum-based chemotherapy
Dosing & Administration	160mg by mouth once daily with or without food
Dosage Form(s)	40mg capsules

# Mobocertinib (Exkivity<sup>®</sup>)

## Mobocertinib

Mechanism of Action	<ul style="list-style-type: none"><li>• Irreversible inhibitor of <i>EGFR</i>ex20ins mutations</li><li>• Leads to decreased proliferation of cells driven by these mutations</li></ul>
PK/PD	<ul style="list-style-type: none"><li>• Half-life of parent drug and active metabolites ~18-24hrs</li><li>• Metabolized by CYP3A</li><li>• Excreted primarily in the feces (76%)</li><li>• No clinically significant differences in PK observed in patients with mild-moderate renal or hepatic dysfunction</li></ul>
Drug Interactions	<ul style="list-style-type: none"><li>• Reduce dose by 50% with concomitant use of moderate CYP3A inhibitor and monitor QTc more frequently</li><li>• Avoid CYP3A inducers</li></ul>

# Mobocertinib (Exkivity®)

Mobocertinib	
Boxed Warning(s)	<ul style="list-style-type: none"><li>• QTc prolongation/Torsades des Pointes</li></ul>
Warnings/Precautions	<ul style="list-style-type: none"><li>• Interstitial lung disease (ILD)/pneumonitis</li><li>• Cardiac toxicity</li><li>• Diarrhea</li><li>• Embryo-fetal toxicity</li></ul>
Common Adverse Effects	<ul style="list-style-type: none"><li>• Diarrhea</li><li>• Rash</li><li>• Nausea/vomiting (moderate-high emetogenicity)</li><li>• Stomatitis</li><li>• Paronychia</li><li>• Dry skin</li><li>• Musculoskeletal pain</li></ul>



# Clinical Trial: Mobocertinib

## Open-label, phase 1/2 trial: EXCLAIM cohort

- Locally advanced/metastatic NSCLC
- *EGFR*ex20ins mutation
- 1-2 prior treatments
- Stable, treated brain mets allowed

Platinum  
Pre-treated (PPP)  
n = 114

EXCLAIM cohort  
n = 96

Mobocertinib  
160mg daily

# Efficacy: Mobocertinib

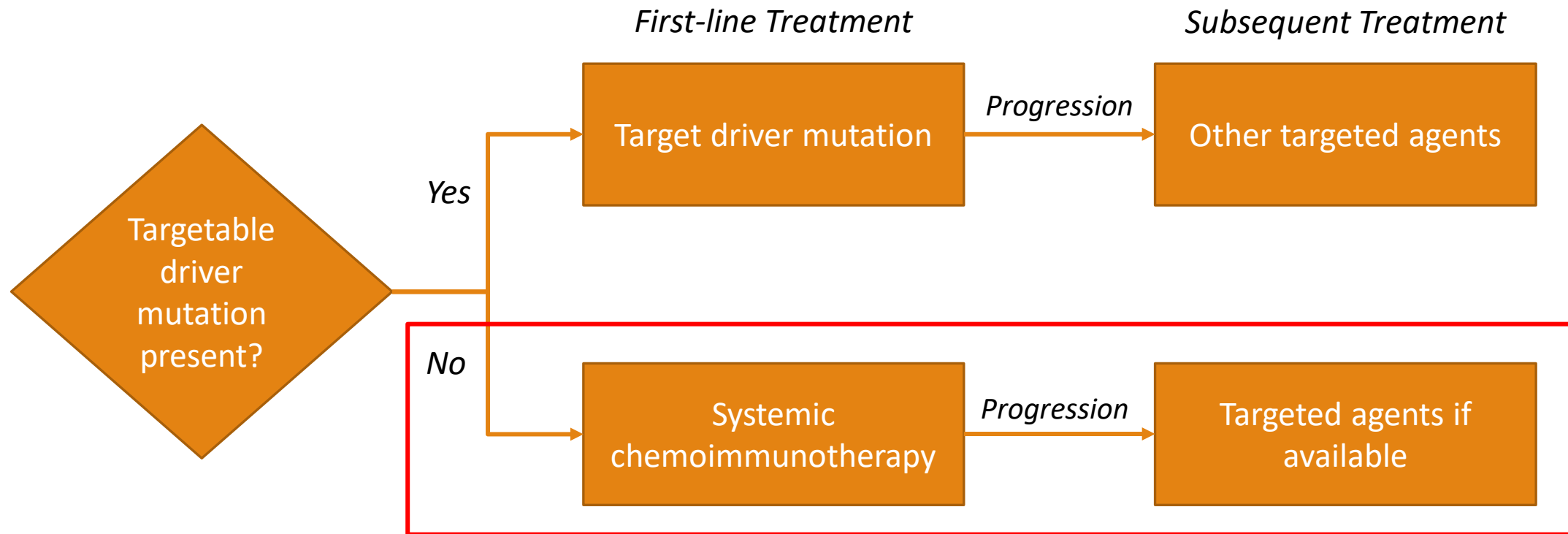
	PPP	EXCLAIM
ORR by IRC	28%	25%
DCR by IRC	78%	76%
Duration of response	17.5 months	Not reached
Time to response	1.9 months	
PFS	7.3 months	
OS	24 months	Not reached

- Brain was first site of progression in 38% of patients with PD and 68% of patients with baseline brain mets

# Safety: Mobocertinib

	PPP		EXCLAIM	
	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)
Any treatment-related AE	99	47	99	42
Diarrhea	91	21	93	16
Rash	45	0	45	0
Paronychia	38	<1	39	1
Vomiting	30	3	26	1
Stomatitis	24	4	27	3
QTc prolongation	11	3	8	3

# Metastatic NSCLC: Treatment Paradigm



**Targeted agents for  
EGFRex20ins mutations:**

- **Amivantamab**
- **Mobocertinib**

# Significance

- *EGFR*ex20ins mutations account for ~4-10% of all EGFR mutations
- *EGFR*ex20 mutations are heterogeneous → generally predict lack of benefit to EGFR TKIs
- Mobocertinib represents an alternative, second-line, oral treatment option for patients with metastatic NSCLC and *EGFR*ex20ins mutations
- Future directions
  - Mobocertinib first-line vs platinum-based chemotherapy

Tisotumab vedotin-tftv

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# Tisotumab vedotin-tftv (Tivdak™)



## Tisotumab vedotin

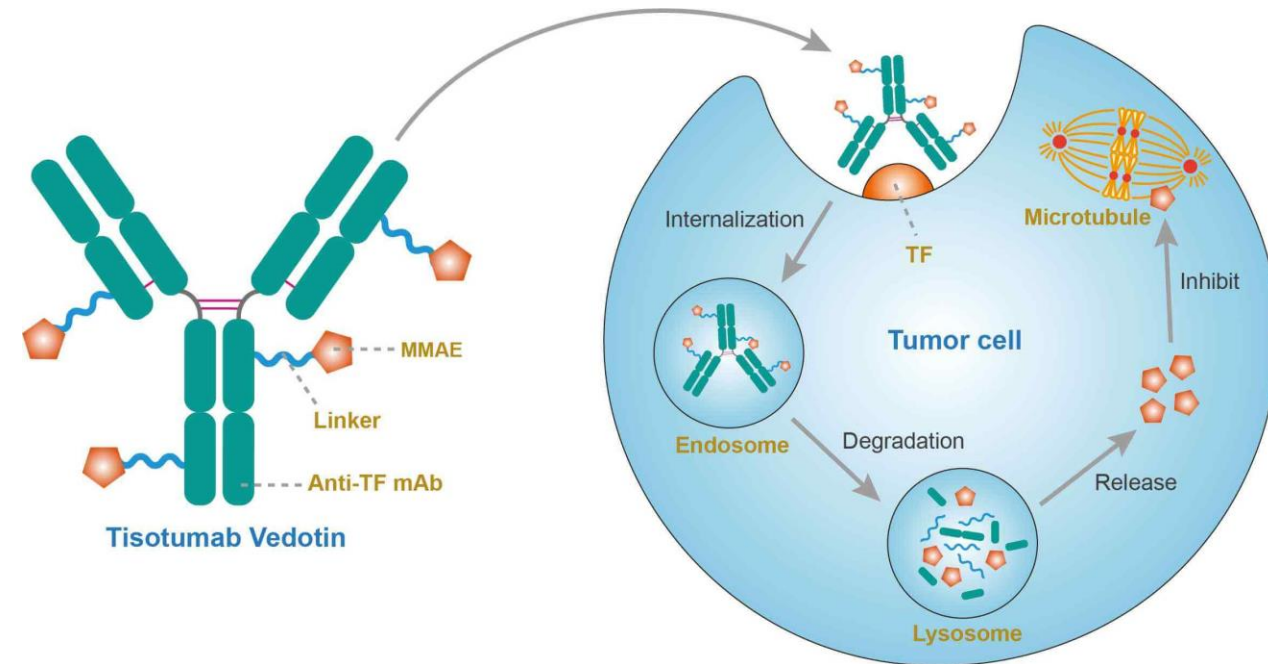
Approval Date	9/20/2021
Indication	Treatment of adult patients with recurrent or metastatic cervical cancer after disease progression on or after chemotherapy
Dosing & Administration	Tisotumab vedotin 2mg/kg (up to a max of 200mg) IV over 30 minutes every 3 weeks
Dosage Form(s)	40mg single dose vial

# Tisotumab vedotin-tftv (Tivdak™)

## Tisotumab vedotin

### Mechanism of Action

- Antibody drug conjugate (ADC) targeted towards tissue factor (TF) on the cell surface
- Tisotumab vedotin internalized by target cell → release of MMAE payload
- MMAE disrupts microtubule network of dividing cells → cell cycle arrest → apoptosis
- Tisotumab vedotin may also mediate antibody-directed cellular phagocytosis and antibody-directed cellular cytotoxicity





# Tisotumab vedotin-tftv (Tivdak™)

## Tisotumab vedotin

### PK/PD

- Unconjugated MMAE is metabolized by CYP3A4 in vitro
- MMAE exposure increased by 37% in patients with mild hepatic dysfunction → no initial dose adjustments recommended
- Avoid use in patients with moderate-severe hepatic dysfunction

### Drug Interactions

- Clinical studies with another ADC show the following interactions:
  - Strong CYP3A4 inhibitor: increased MMAE exposure by 34%
  - Strong CYP3A4 inducer: decreased MMAE exposure by 46%
- Monitor closely for side effects in patients taking strong CYP3A4 inhibitors

# Tisotumab vedotin-tftv (Tivdak™)

## Tisotumab vedotin

Boxed Warning(s)	<p>Ocular toxicity: can lead to severe vision loss and corneal ulceration</p> <ul style="list-style-type: none"> <li>• Recommend eye exam at baseline and prior to each dose</li> <li>• Steroid eye drops prior to infusion and for 72 hrs after infusion</li> <li>• Vasoconstrictor eye drops prior to infusion</li> <li>• Cooling eye pads during infusion</li> <li>• Lubricating eye drops during therapy and for 30 days after last dose</li> <li>• Avoid wearing contact lenses for entire duration of therapy</li> </ul>		
Warnings/Precautions	<ul style="list-style-type: none"> <li>• Peripheral neuropathy</li> <li>• Hemorrhage</li> <li>• Pneumonitis</li> <li>• Embryo-fetal toxicity</li> </ul>		
Common Adverse Effects	<ul style="list-style-type: none"> <li>• Alopecia</li> <li>• Epistaxis</li> <li>• Nausea (low emetogenicity)</li> </ul>	<ul style="list-style-type: none"> <li>• Conjunctivitis</li> <li>• Fatigue</li> <li>• Anemia</li> </ul>	<ul style="list-style-type: none"> <li>• Muscle/joint pain</li> <li>• Dry eyes</li> <li>• Peripheral neuropathy</li> </ul>

# Clinical Trial: innovaTV 204/GOG-3023/ENGOT-cx6

## Open-label, phase 2 trial

- Recurrent or metastatic cervical cancer
- Progressed during/after doublet chemo ± bevacizumab
- ≤2 regimens for recurrent or metastatic disease

Tisotumab vedotin 2mg/kg  
(up to 200mg) Q3wks

# Efficacy: innovaTV 204/GOG-3023/ENGOT-cx6

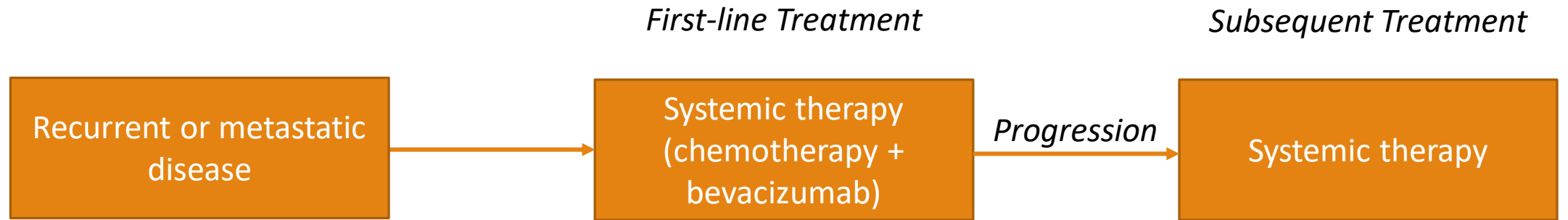
	<b>Tisotumab vedotin N =101</b>
ORR	24%
DCR	72%
Duration of response	8.3 months
Time to response	1.4 months
PFS	4.2 months
OS	12.1 months

# Safety: innovaTV 204/GOG-3023/ENGOT-cx6

	Tisotumab vedotin	
	Any Grade (%)	Grade $\geq 3$ (%)
Any treatment-related AE	93	28
Ocular AEs	53	2
Conjunctivitis	26	0
Dry Eyes	23	0
Keratitis	11	0
Bleeding AEs	39	2
Epistaxis	30	0
Vaginal hemorrhage	7	0
Hematuria	3	0

	Tisotumab vedotin	
	Any Grade (%)	Grade $\geq 3$ (%)
Peripheral neuropathy	33	7
Alopecia	38	0
Nausea	27	0
Myalgia	15	0
Anemia	13	1
Arthralgia	12	0
Neutropenia	4	3

# Metastatic Cervical Cancer: Treatment Paradigm



## Preferred regimens:

- Anti PD-1 agents if PD-L1+ (Category 2A)

## Other:

- Tisotumab vedotin (Category 2A)
- Single-agent chemotherapy (Category 2B)

# Significance

- No standard second-line treatment option established for metastatic cervical cancer patients who are not PD-L1+
- Tisotumab vedotin serves as an effective treatment option after progression on chemotherapy + bevacizumab
  - Tisotumab vedotin ORR 24% vs pembrolizumab ORR 14.6% in KEYNOTE-158
- Future directions
  - Tisotumab vedotin in combination with other agents for cervical cancer
  - Use in other solid tumors

Tebentafusp-tebn

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# Tebentafusp-tebn (Kimmtrak<sup>®</sup>)



## Tebentafusp

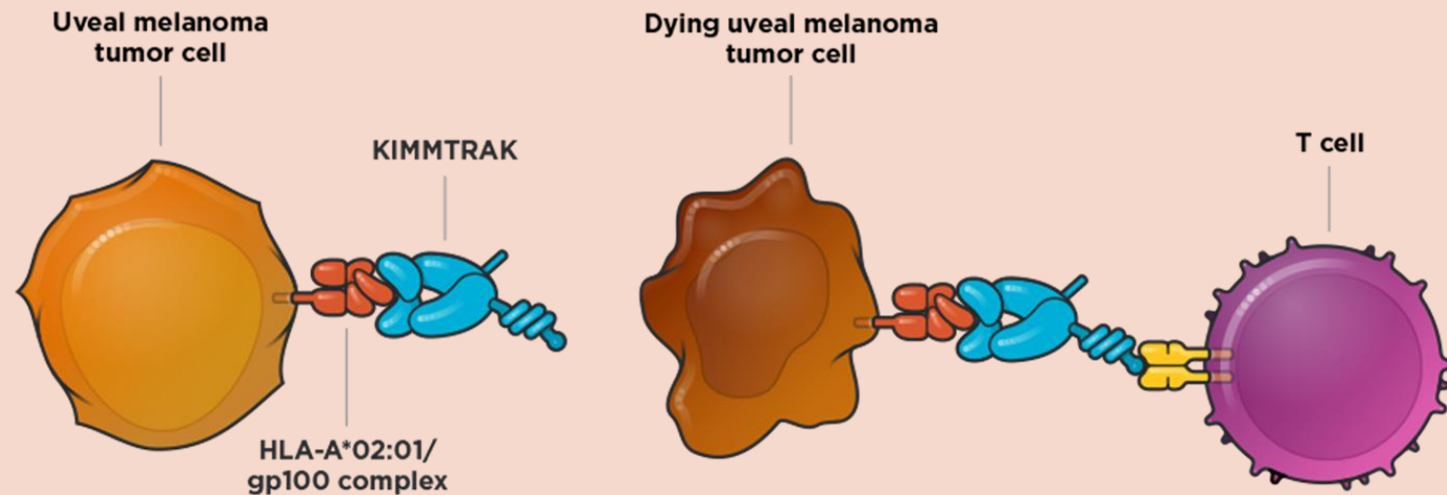
Approval Date	1/26/2022
Indication	Treatment of HLA-A*02:01-positive adults with unresectable or metastatic uveal melanoma
Dosing	<ul style="list-style-type: none"><li>• Day 1: 20mcg</li><li>• Day 8: 30mcg</li><li>• Day 15: 68mcg</li><li>• 68mcg once every week thereafter</li></ul>
Administration	<ul style="list-style-type: none"><li>• IV infusion over 15-20 minutes</li><li>• Monitor patients for at least 16hrs after the first 3 infusions</li><li>• If no <math>\geq</math>grade 2 hypotension during or after 3<sup>rd</sup> infusion, administer in outpatient setting and monitor patients for at least 30 minutes after each infusion</li></ul>

# Tebentafusp-tebn (Kimmtrak<sup>®</sup>)

## Tebentafusp

### Mechanism of Action

- Bi-specific T-cell engager directed towards gp-100 peptide presented by HLA-A\*02:01 on the surface of uveal melanoma tumor cells
- T cells release inflammatory cytokines, cytolytic proteins → direct lysis of tumor cells



# Tebentafusp-tebn (Kimmtrak<sup>®</sup>)

## Tebentafusp

<p>Boxed Warning(s)</p>	<ul style="list-style-type: none"> <li>• Cytokine release syndrome (CRS) - temperature <math>\geq 38^{\circ}\text{C}</math> with:</li> </ul>		
	<p><b>Moderate</b></p> <ul style="list-style-type: none"> <li>• Hypotension responding to fluids</li> <li>• Hypoxia needing LFNC</li> </ul>	<p><b>Severe</b></p> <ul style="list-style-type: none"> <li>• Hemodynamic instability requiring pressors</li> <li>• Hypoxia needing HFNC/face mask</li> </ul>	<p><b>Life-threatening</b></p> <ul style="list-style-type: none"> <li>• Hemodynamic instability requiring multiple pressors</li> <li>• Hypoxia requiring intubation</li> </ul>
	<ul style="list-style-type: none"> <li>• Administer IV steroids (ex. methylprednisolone 2mg/kg or equivalent) for severe or life-threatening CRS</li> <li>• For persistent/recurrent moderate CRS or severe CRS, pre-medicate with dexamethasone 4mg 30 minutes before next infusion</li> </ul>		
<p>Warnings/Precautions</p>	<ul style="list-style-type: none"> <li>• Skin reactions</li> <li>• Elevated liver enzymes</li> <li>• Embryo-fetal toxicity</li> </ul>		
<p>Common Adverse Effects</p>	<ul style="list-style-type: none"> <li>• CRS</li> <li>• Rash</li> <li>• Fevers</li> </ul>	<ul style="list-style-type: none"> <li>• Itching</li> <li>• Chills</li> <li>• Nausea</li> </ul>	<ul style="list-style-type: none"> <li>• Fatigue</li> <li>• Hypotension</li> <li>• Headaches</li> </ul>

# Clinical Trial: IMCgp100-202

## Open-label, phase 3 trial

- Metastatic uveal melanoma
- HLA-A\*02:01-positive
- No prior systemic or liver-directed therapy
- No symptomatic CNS mets, autoimmune diseases on steroids, immunosuppressive treatment

Randomized 2:1

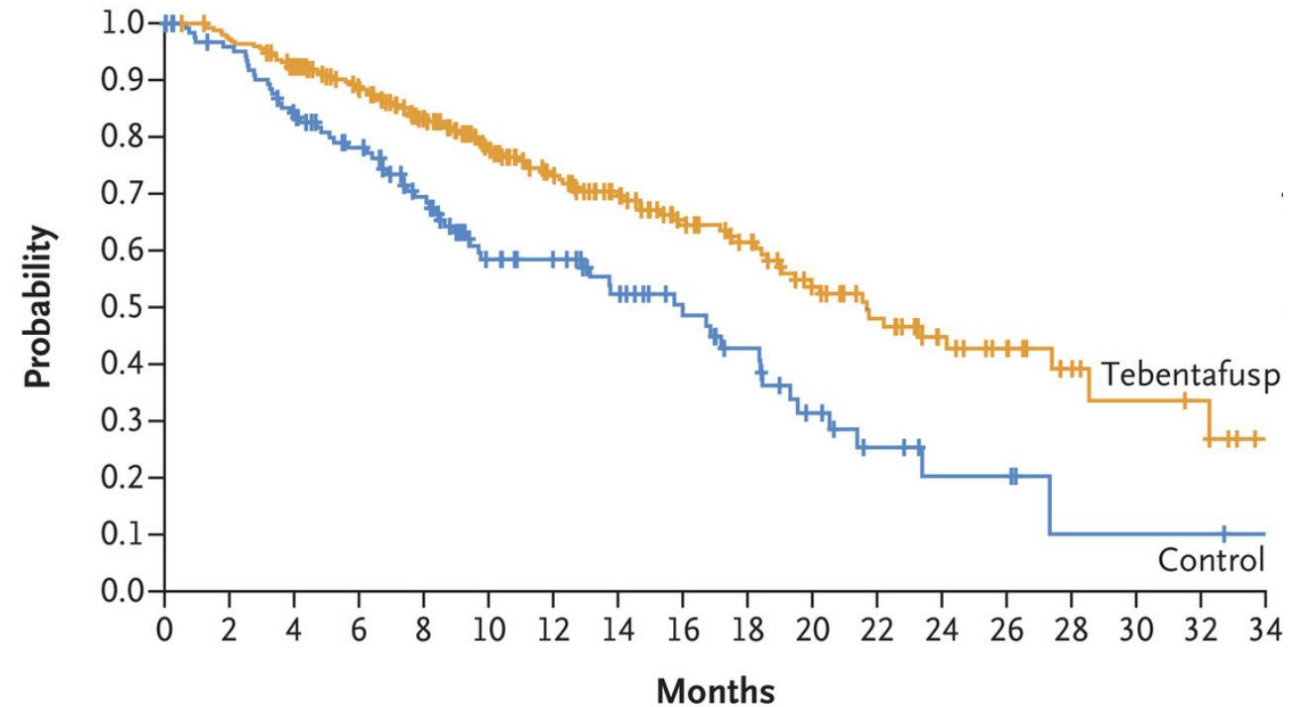
**Tebentafusp** 20mcg on D1, 30mcg on D8, and 68mcg weekly thereafter

- **Pembrolizumab** 2mg/kg (up to 200mg) or 200mg flat dose on Q3wks (**82%**)
- **Ipilimumab** 3mg/kg on Q3wks x 4 doses (**13%**)
- **Dacarbazine** 1000mg/m<sup>2</sup> Q3wks (**6%**)

# Efficacy: IMCgp100-202

	<b>Tebentafusp n = 252</b>	<b>Control n = 126</b>
OS	21.7 months	16.0 months
	HR 0.51 (95% CI, 0.37-0.71; P<0.001)	
PFS	3.3 months	2.9 months
	HR 0.73 (95% CI, 0.58-0.94)	
ORR	9%	5%
DCR	46%	27%

Overall Survival

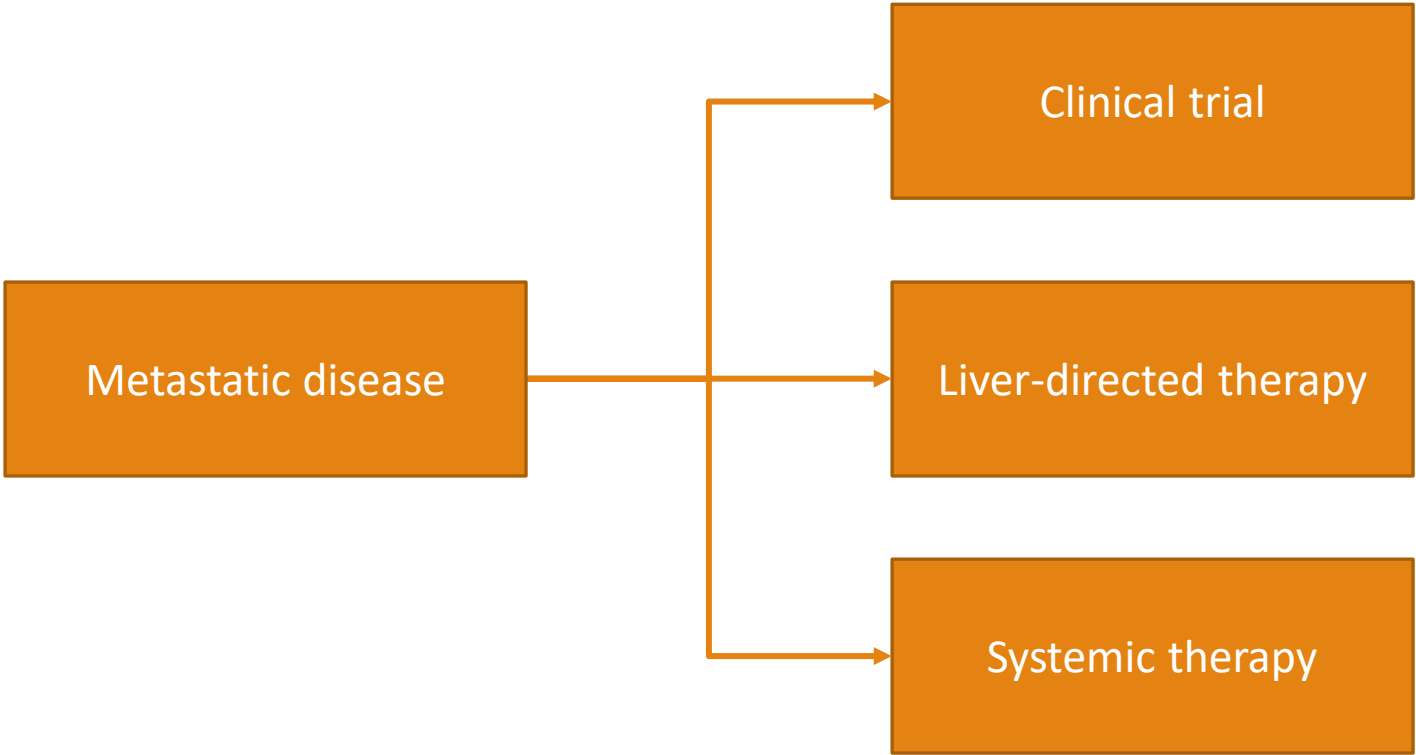


# Safety: IMCgp100-202

	Tebentafusp		Control	
	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)
Any treatment-related AE	99	44	82	17
CRS	89	1	3	0
Rash	83	18	24	0
Pruritus	76	4	3	0
Chills	69	4	21	0
Hypotension	47	<1	3	0
Vomiting	26	<1	6	0
Headache	22	<1	3	1
Increased ALT	18	3	7	2

- 57% of tebentafusp-related AEs occurred during the first 4 weeks of treatment

# Metastatic Uveal Melanoma: Treatment Paradigm



**Tebentafusp in HLA A\*02:01-positive patients (Category 1)**

# Significance

- Distant metastatic uveal melanoma associated with poor prognosis (5-yr OS <20%)
- Prior treatments have not definitively improved outcomes
- Tebentafusp represents the first FDA-approved treatment for unresectable or metastatic uveal melanoma
- Liver-directed therapy or ipilimumab/nivolumab may be preferred for patients with symptomatic liver metastases
- Future directions
  - Tebentafusp + immunotherapy in cutaneous melanoma



# Nivolumab and Relatlimab-rmbw

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# Nivolumab and Relatlimab-rmbw (Opdualag™)



## Nivolumab and Relatlimab

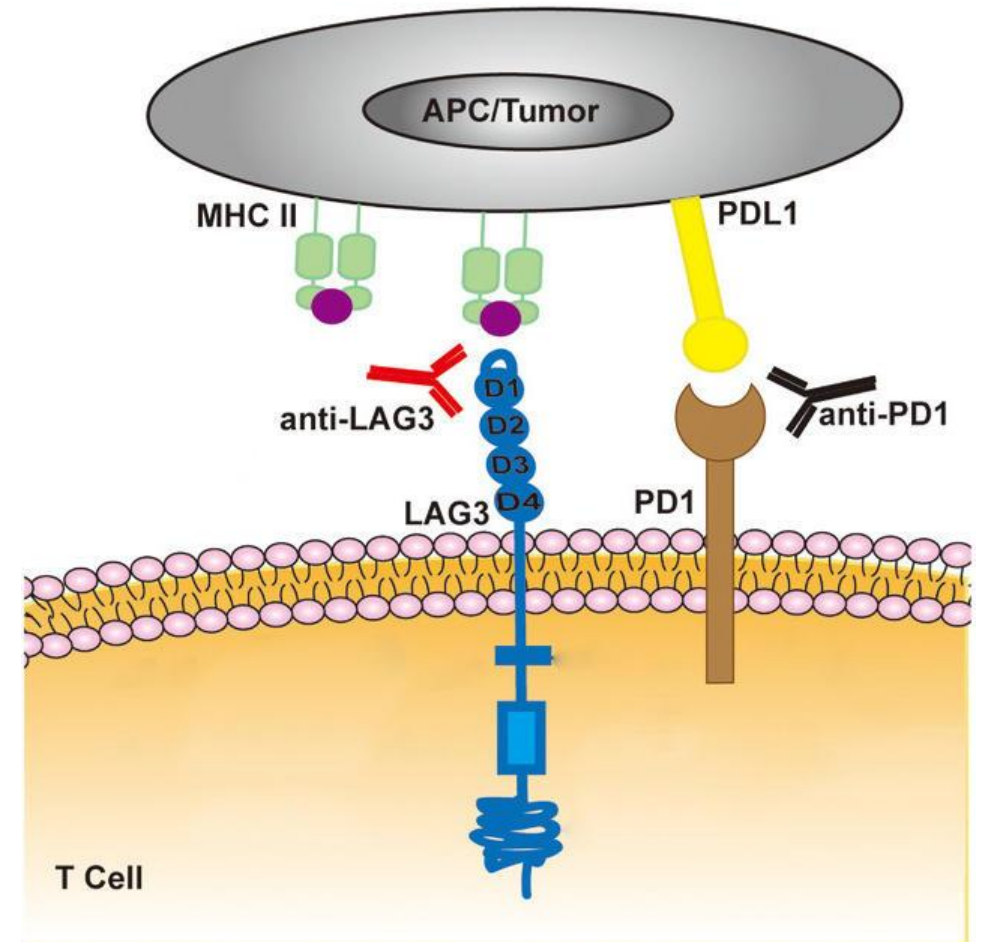
Approval Date	3/18/2022
Indication	Treatment of adult and pediatric patients $\geq 12$ years old with metastatic or unresectable melanoma
Dosing & Administration	480mg nivolumab/160mg relatlimab IV over 30 minutes every 4 weeks
Dosage Form(s)	240mg nivolumab/80mg relatlimab per 20 mL single-dose vials

# Nivolumab and Relatlimab-rmbw (Opdualag™)

## Nivolumab and Relatlimab

### Mechanism of Action

- Nivolumab binds to the PD-1 receptor on T cells and reduces PD-1 mediated inhibition of the immune response
- Relatlimab binds to the LAG-3 receptor on T cells and reduces LAG-3 mediated inhibition of the immune response
- Combination of both leads to increased T cell activation → T cells block tumor growth and promote tumor regression



# Nivolumab and Relatlimab-rmbw (Opdualag™)

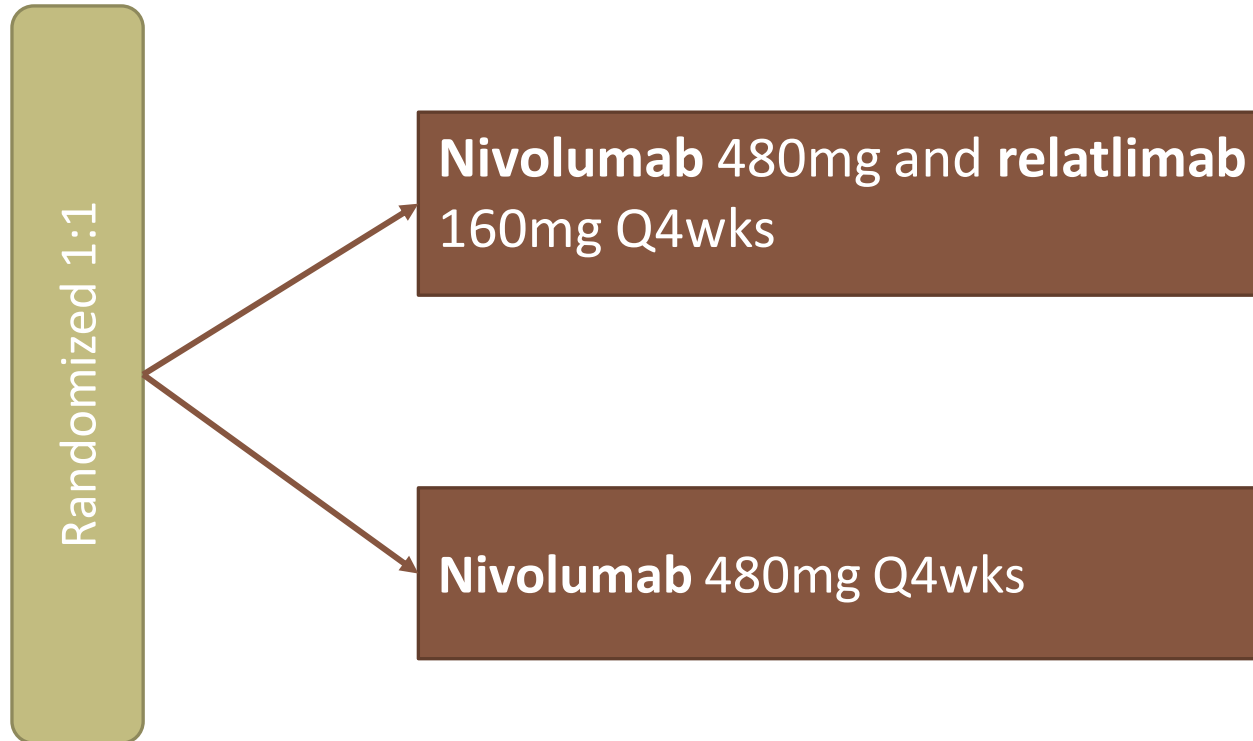
## Nivolumab and Relatlimab

Boxed Warning(s)	None
Warnings/Precautions	<ul style="list-style-type: none"><li>• Immune-mediated adverse reactions (irAEs)</li><li>• Infusion-related reaction</li><li>• Complications of allogeneic HSCT</li><li>• Embryo-fetal toxicity</li></ul>
Common Adverse Effects	<ul style="list-style-type: none"><li>• Musculoskeletal pain</li><li>• Fatigue</li><li>• Rash</li><li>• Pruritus</li><li>• Diarrhea</li></ul>

# Clinical Trial: RELATIVITY-047

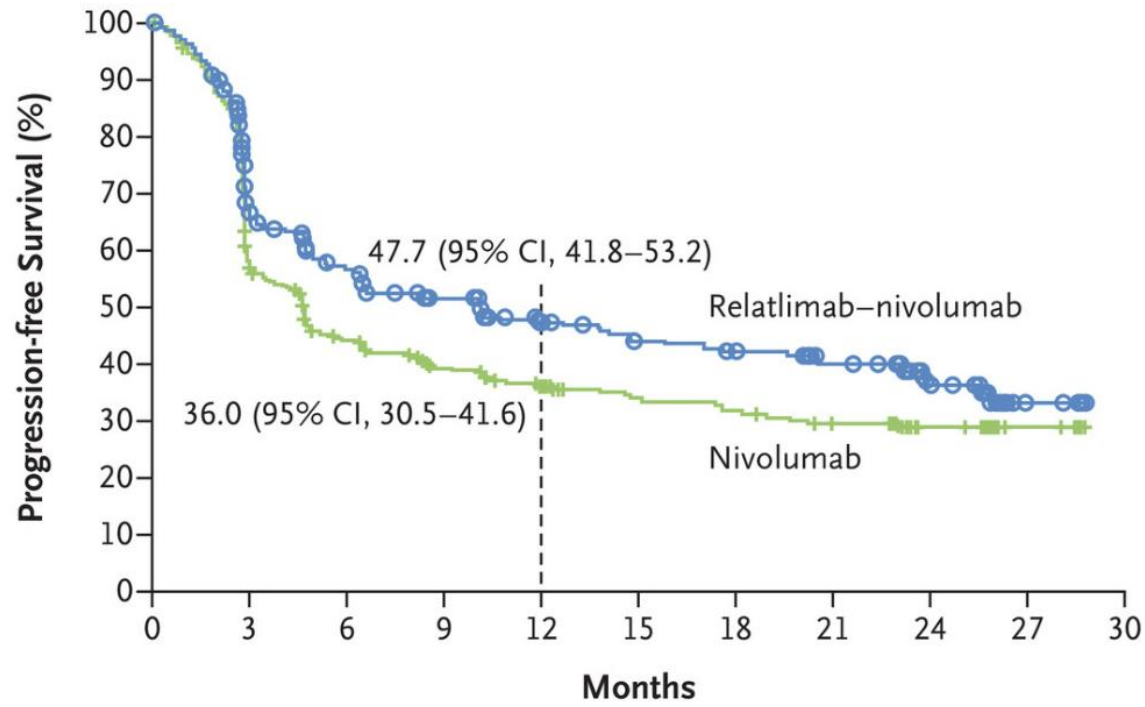
## Randomized, double-blind, phase 2-3 trial

- ≥12 years old
- Previously untreated
- Unresectable stage III/IV melanoma
- Prior PD-1, CTLA-4, BRAF or MEK inhibitors allowed if treatment completed ≥6 months before recurrence



# Efficacy: RELATIVITY-047

	Nivolumab and Relatlimab n = 355	Nivolumab n = 359
PFS (months)	10.1	4.6
	HR 0.75 (95% CI, 0.62-0.92; P=0.006)	



## ASCO Data

	Nivolumab and Relatlimab n = 355	Nivolumab n = 359
PFS (months)	10.2	4.6
	HR 0.78 (95% CI, 0.6-0.9)	
OS (months)	Not reached	34.1
	HR 0.80 (95% CI, 0.6-1.0; P=0.0593)	
ORR	43.1%	32.6%
CR	16.3%	14.2%

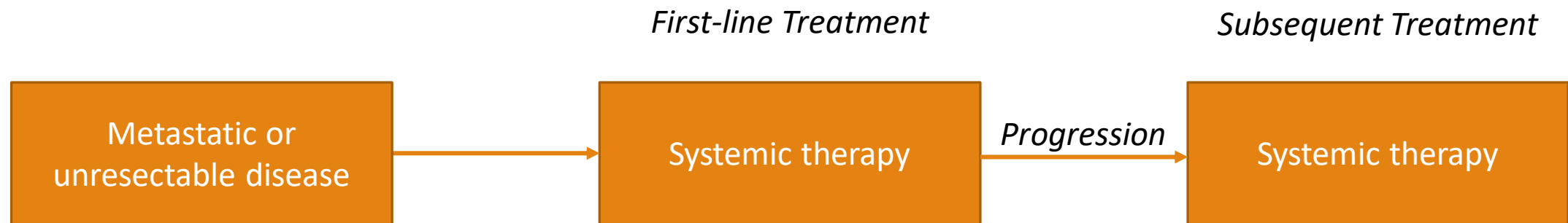
Tawbi HA et al. N Engl J Med. 2022;386(1):24-34.

Long GV et al. J Clin Oncol 2022;40[36\_suppl]:360385-360385.

# Safety: RELATIVITY-047

	Nivolumab and Relatlimab		Nivolumab	
	Any Grade (%)	Grade $\geq$ 3 (%)	Any Grade (%)	Grade $\geq$ 3 (%)
Any treatment-related AE	81.1	18.9	69.9	9.7
Infusion-related reactions	5.9	-	3.6	-
<i>irAEs</i>				
Hypothyroidism/thyroiditis	18	0	13.9	0
Rash	9.3	0.6	6.7	1.4
Diarrhea/colitis	6.8	1.1	3.1	1.4
Hyperthyroidism	6.2	0	6.7	0
Hepatitis	5.6	3.9	2.5	1.1
Pneumonitis	3.7	0.6	1.7	0.6
Myocarditis	1.7	0.6	0.6	0

# Metastatic Cutaneous Melanoma: Treatment Paradigm



## Preferred regimens:

- **Anti PD-1 agents (Category 1)**
- **Nivolumab/ipilimumab (Category 1)**
- **Nivolumab and relatlimab (Category 2A)**
- **BRAF/MEK inhibitors (Category 1)**



# Significance

- Nivolumab and relatlimab represents a new first-line dual immunotherapy treatment option for unresectable or metastatic cutaneous melanoma
- Nivolumab and relatlimab appears less toxic than nivolumab/ipilimumab
- Future directions
  - Mature data
  - Nivolumab and relatlimab being studied in multiple indications

	Nivolumab and Relatlimab (RELATIVITY-047)		Nivolumab and Ipilimumab (CHECKMATE 067)	
	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)
Any treatment-related AE	81.1	18.9	95.5	55.5
Treatment-related AE leading to discontinuation	14.6	8.5	36.4	29.4
Rash	9.3	0.6	40.3	4.8
Diarrhea	6.8	1.1	44.1	9.3

Lutetium  
( $^{177}\text{Lu}$ ) vipivotide tetraxetan

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# Lutetium (<sup>177</sup>Lu) vipivotide tetraxetan (Pluvicto™)



## Lutetium (<sup>177</sup>Lu) vipivotide tetraxetan

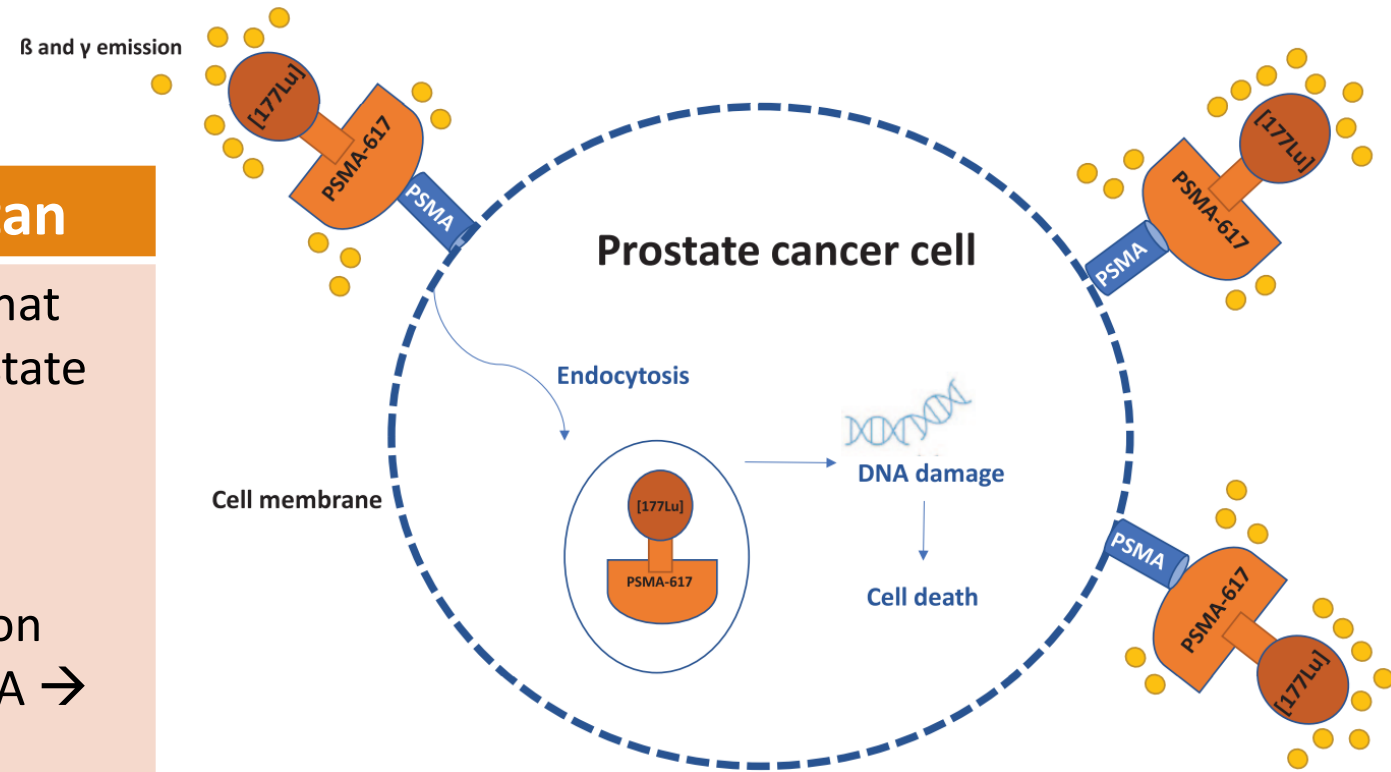
Approval Date	3/23/2022
Indication	Treatment of adult patients with PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with anti-androgen therapy and taxane-based chemotherapy
Patient Selection	PSMA-positive by LOCAMETZ® Ga-68 PET scan or other PSMA-11 imaging agent
Dosing & Administration	7.4 GBq (200 mCi) every 6 weeks for up to 6 doses
Dosage Form(s)	1000 mBq/mL (27 mCi/mL) single-dose vial

# Lutetium (<sup>177</sup>Lu) vipivotide tetraxetan (Pluvicto™)

## Lutetium (<sup>177</sup>Lu) vipivotide tetraxetan

### Mechanism of Action

- Radioligand therapeutic agent that targets PSMA on surface of prostate cancer cells
- Lutetium (<sup>177</sup>Lu) vipivotide tetraxetan absorbed by cell → beta-emission from lutetium-177 damages DNA → cell death



# Lutetium (177Lu) vipivotide tetraxetan (Pluvicto™)

Lutetium (177Lu) vipivotide tetraxetan	
Boxed Warning(s)	None
Warnings/Precautions	<ul style="list-style-type: none"><li>• Risk from radiation exposure</li><li>• Myelosuppression</li><li>• Renal toxicity</li><li>• Embryo-fetal toxicity</li><li>• Infertility</li></ul>
Common Adverse Effects	<ul style="list-style-type: none"><li>• Fatigue</li><li>• Dry mouth</li><li>• Nausea</li><li>• Anemia</li><li>• Constipation</li></ul>

# Clinical Trial: VISION

## Open-label, phase 3 trial

- PSMA+ mCRPC: at least one PSMA(+) lesion and no dominant PSMA(-) lesions
- Disease progression after  $\geq 1$  AR-pathway inhibitor and one or both taxane regimens

Randomized 2:1

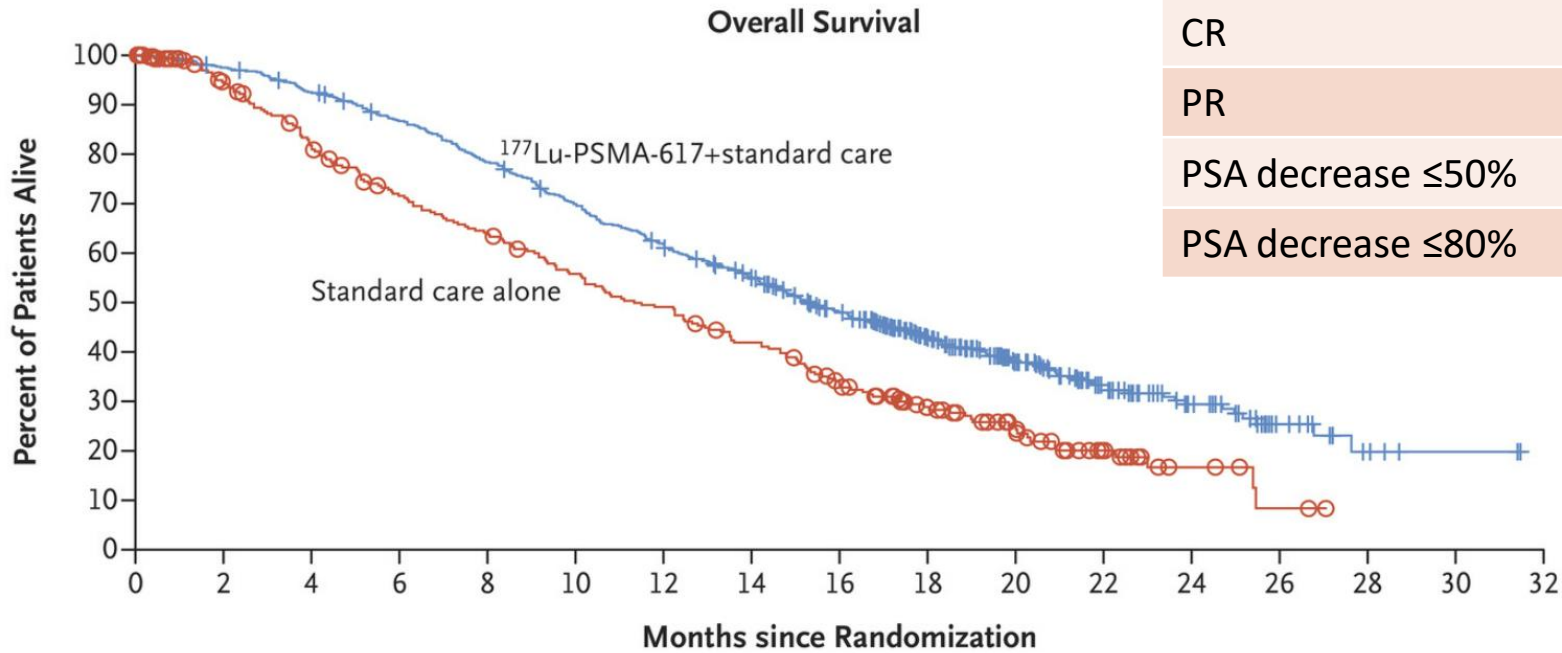
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graph LR; A[Randomized 2:1] --> B[Lutetium (177Lu) vipivotide tetraxetan 7.4 GBq Q6wks for up to 6 cycles + standard of care]; A --> C[Standard of care (excluded chemotherapy, radioisotopes, IO, investigational drugs at time of trial design)];
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**Lutetium (<sup>177</sup>Lu) vipivotide tetraxetan**  
7.4 GBq Q6wks for up to 6 cycles +  
standard of care

**Standard of care** (excluded chemotherapy,  
radioisotopes, IO, investigational drugs at  
time of trial design)

# Efficacy: VISION

	<sup>177</sup> Lu-PSMA-617 + SOC n = 551	SOC n = 280
Imaging-based PFS <small><sup>177</sup>Lu-PSMA-617 + SOC n = 385; SOC n = 196</small>	8.7 months	3.4 months
	HR 0.40 (99.2% CI, 0.29-0.57; P<0.001)	
OS	15.3 months	11.3 months
	HR 0.62 (95% CI, 0.52-0.74; P<0.001)	
Time to first symptomatic skeletal event or death	11.5 months	6.8 months
CR	9.2%	0%
PR	41.8%	3%
PSA decrease ≤50%	46%	7.1%
PSA decrease ≤80%	33%	2%

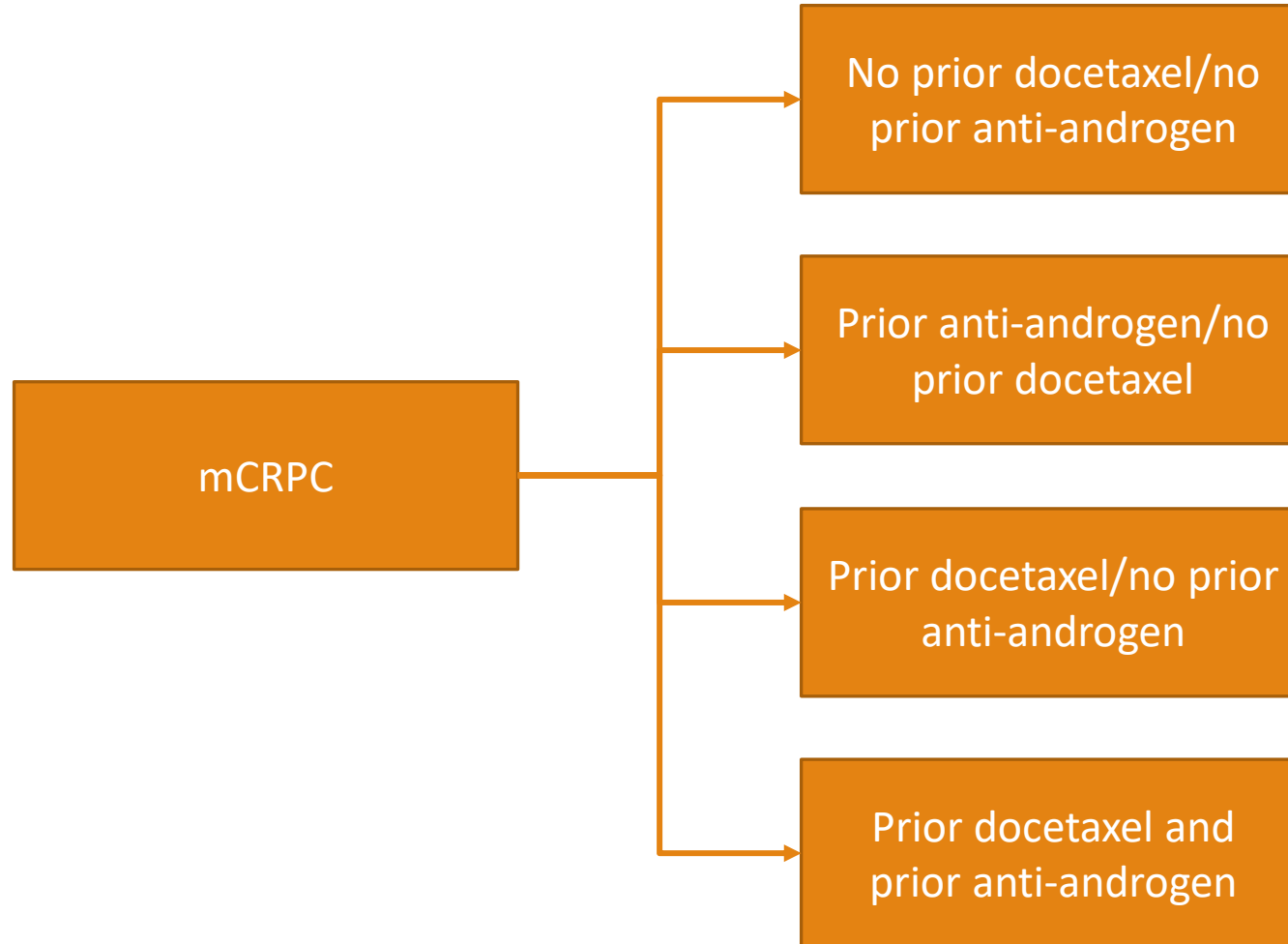


# Safety: VISION

	<sup>177</sup> Lu-PSMA-617 + SOC		SOC	
	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)
Any treatment-related AE	98.1	52.7	82.9	38
Fatigue	43.1	5.9	22.9	1.5
Dry mouth	38.8	0	0.5	0
Anemia	31.8	12.9	13.2	4.9
Back pain	23.4	3.2	14.6	3.6
Constipation	20.2	1.1	11.2	0.5
Vomiting	18.9	0.9	6.3	0.5
Thrombocytopenia	17.2	7.9	4.4	1.0
Lymphopenia	14.2	7.8	3.9	0.5
Leukopenia	12.5	2.5	2.0	0.5



# mCRPC: Treatment Paradigm



## Useful in certain circumstances

- <sup>177</sup>Lu-PSMA-617 for PSMA+ patients (Category 1)
- Olaparib, pembrolizumab, radium-223, rucaparib and others

## Preferred regimens

- Cabazitaxel
- Docetaxel rechallenge

# Significance

- Lutetium ( $^{177}\text{Lu}$ ) vipivotide tetraxetan is a new treatment option for patients with mCRPC with PSMA+ lesions
- Serves as an alternative to cabazitaxel for patients who received prior docetaxel and prior hormonal therapy
  - TheraP trial showed similar OS between  $^{177}\text{Lu}$ -PSMA-617 and cabazitaxel: 19.1 vs 19.6 months (HR 0.97; P = 0.99)
- Future directions
  - $^{177}\text{Lu}$ -PSMA-617 + other agents for mCRPC
  - $^{177}\text{Lu}$ -PSMA-617 for oligometastatic CSPC

# Conclusion

- Several novel agents have been approved for the treatment of solid tumors in the last year, representing new options in the first- and subsequent-line treatment setting
- Future studies will show mature OS data and may further expand indications for these drugs

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# Thank you!

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Questions?

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