

Spotlight on XTX101: a Novel, Fc-Enhanced, Tumor-Activated anti-CTLA-4

August 17, 2023

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Today's Agenda

CTLA-4 Background

CTLA-4 Biology &
Opportunity Associated
with TREG Depletion

XTX101

Fc-Enhanced,
Tumor-Activated
anti-CTLA-4
Product Candidate

XTX101 Monotherapy Data

Phase 1 A/B
Monotherapy Data &
Clinical Case

XTX101 Development Plan

Combination with
anti-PD-L1 in
MSS CRC

Followed by Q&A, submit questions via chat function

Today's Speakers

Featured Key Opinion Leader



Diwakar Davar, MBBS, M.Sc

Diwakar Davar, MBBS, M.Sc is the Associate Professor of Medicine, Clinical Director, Melanoma and Skin Cancer Program, UPMC Hillman Cancer Center. He specializes in the management of advanced melanoma and the development of early phase studies to test novel immunotherapeutic approaches to treat advanced cancers.

Dr. Davar is board-certified in internal medicine and medical oncology. He received his medical degree from National University of Singapore and completed both his residency and fellowship at UPMC.

Dr. Davar is a member of many professional organizations, including the American Association for Cancer Research, American Society of Clinical Oncology, Allegheny County Medical Society, American College of Physicians, and Singapore Medical Association.

Xilio Management Speakers



René Russo, Pharm. D.

Chief Executive Officer



Uli Bialucha, Ph.D.

Chief Scientific Officer



Katarina Luptakova, M.D.

SVP, Medical



Martin Huber, M.D.

President and Head of R&D

Immuno-Oncology Therapy has Curative Potential but is Often Limited by Systemic Toxicity

- Immuno-oncology (IO) therapies have **transformed the treatment landscape** and long-term outlook for some patients with advanced cancer
- Treatment potential for some of the most exciting IO targets has been impeded by **dose-limiting systemic toxicity**

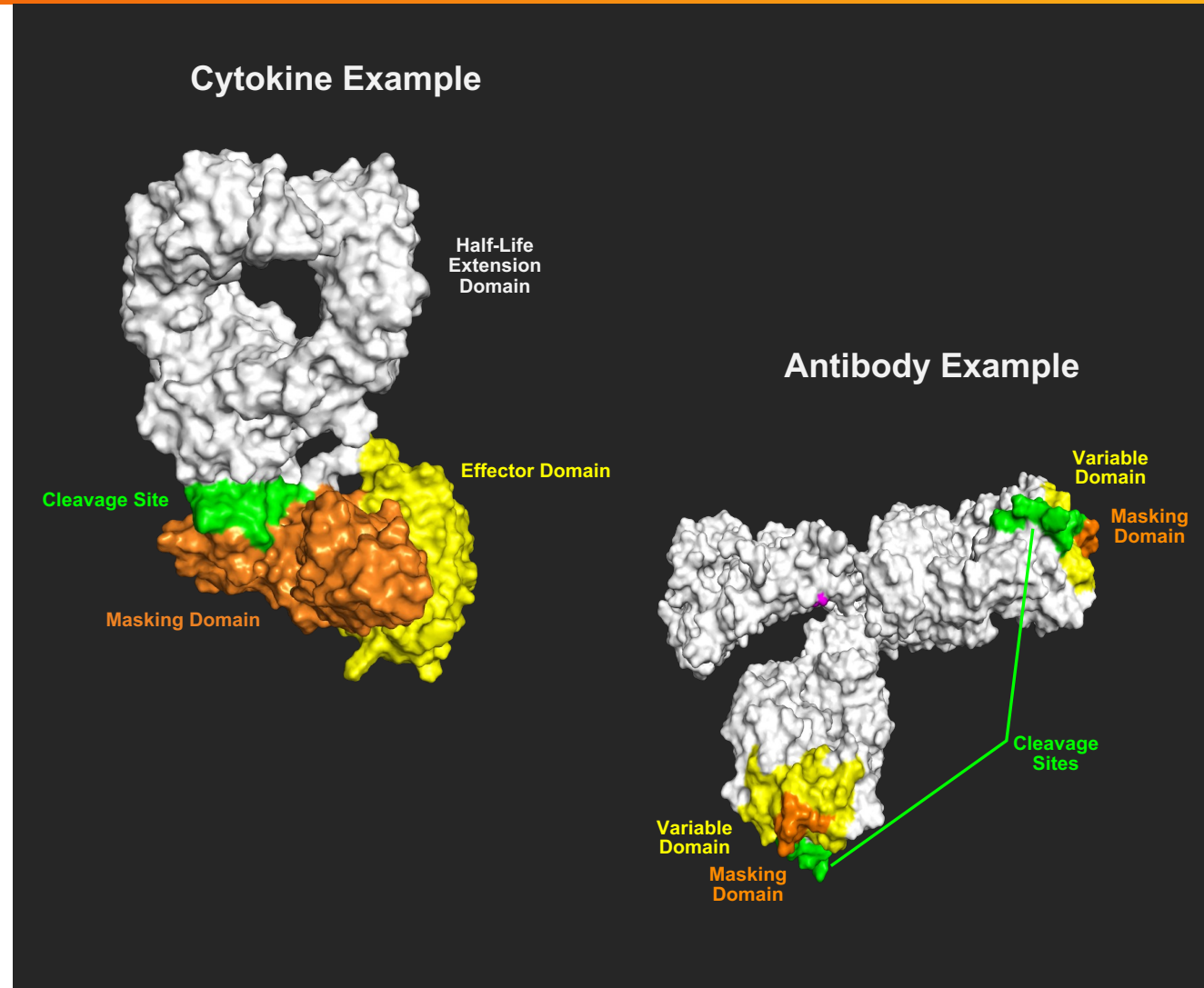


Xilio (ex-il-ee-oh) believes the next revolution in IO cancer therapies will **trick tumors into activating their own treatments**, while simultaneously **sparing healthy tissues and cells**

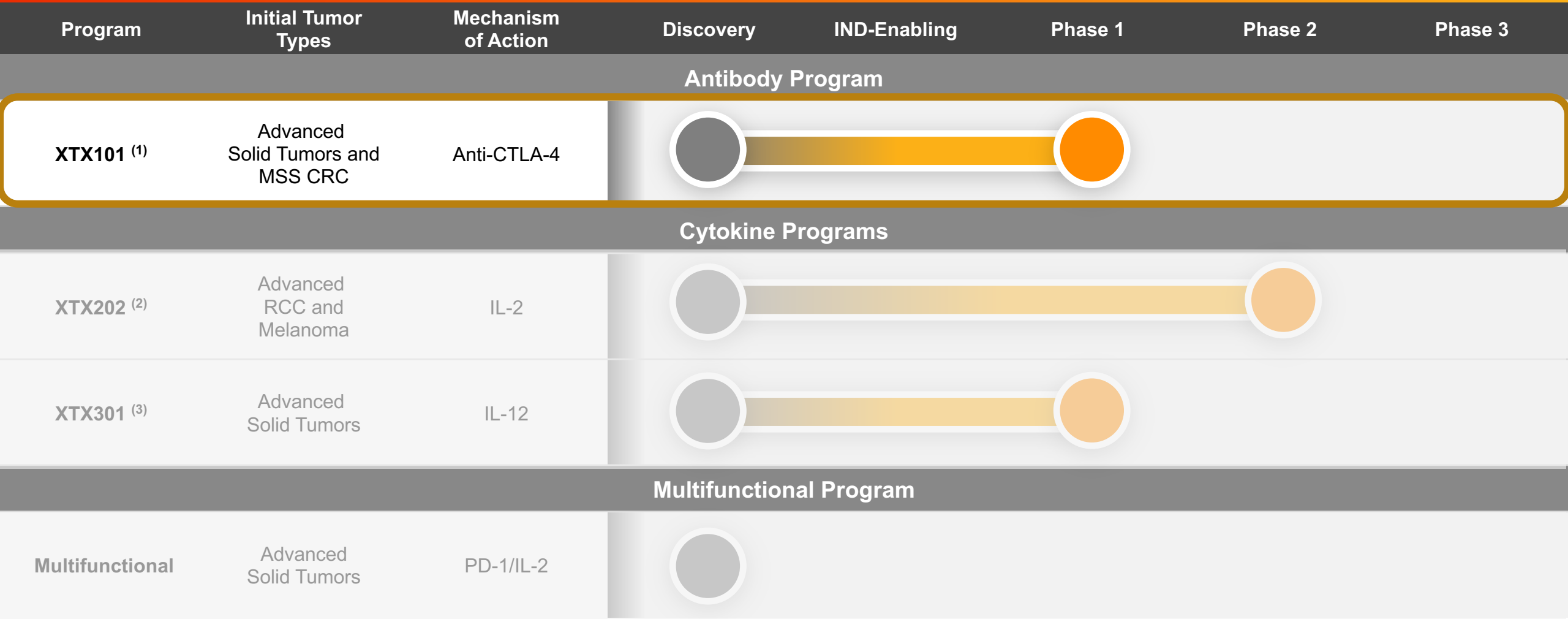
The Critical Challenge: Maximizing Efficacy While Improving Tolerability

Xilio's Novel Tumor-Activated Molecules Are Designed to Overcome the Limitations of Systemically Active Treatments

- **Harness and focus** the power of the immune system to fight cancer
- Novel design to **outsmart tumors** – using tumor growth activity against itself
 - Tumor proteases **activate a switch** in molecules to unleash active agent inside tumor microenvironment (TME)
- Each molecule **custom-designed** using our proprietary geographically precise solutions (GPS) platform **for tumor-selectivity** with a masking domain that is designed to prevent interaction with healthy tissue and cells
 - Molecules are activated by tumor's dysregulated matrix metalloproteases (MMPs)



Building a Pipeline of Novel, Tumor-Activated Immuno-Oncology Therapies



1. Xilio plans to evaluate XTX101 in combination with atezolizumab (Tecentriq®) in a Phase 1/2 clinical trial under a clinical trial collaboration with Roche. The Phase 1 portion is designed to assess the safety and tolerability of the combination in dose escalation in patients with advanced solid tumors, and the planned Phase 2 portion is designed to assess the safety and efficacy of the combination in patients with MSS CRC.

2. Initially evaluating XTX202 as a monotherapy in patients with unresectable or metastatic melanoma and metastatic RCC prior to evaluating XTX202 in combination with an anti-PD-1/PD-L1 for the treatment of patients with NSCLC or potential expansion into additional cancer indications as a monotherapy or combination therapy.

3. Initially plan to evaluate XTX301 as a monotherapy for the treatment of advanced solid tumors.

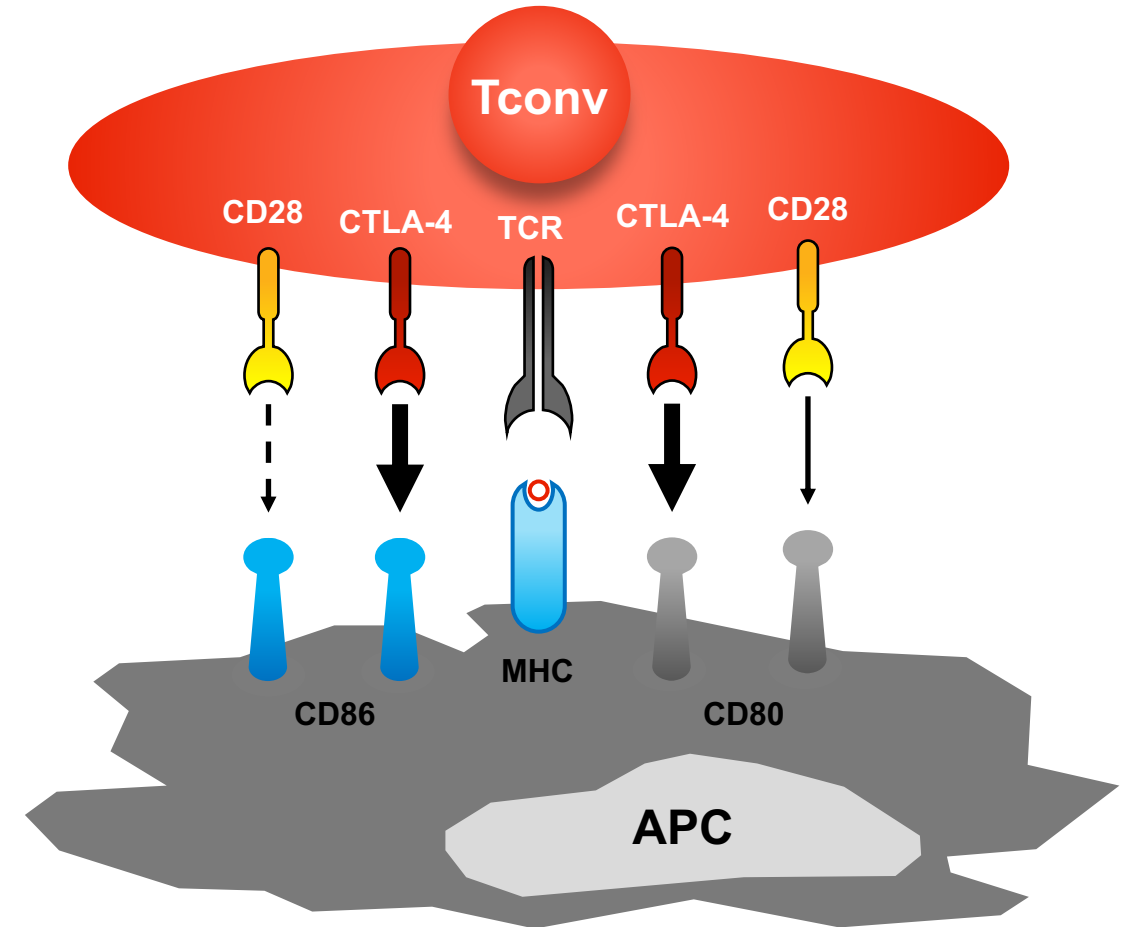
NSCLC: non-small cell lung cancer; RCC: renal cell carcinoma.



CTLA-4 Blockade

CTLA-4 Blockade in Cancer and Cancer Immunotherapy

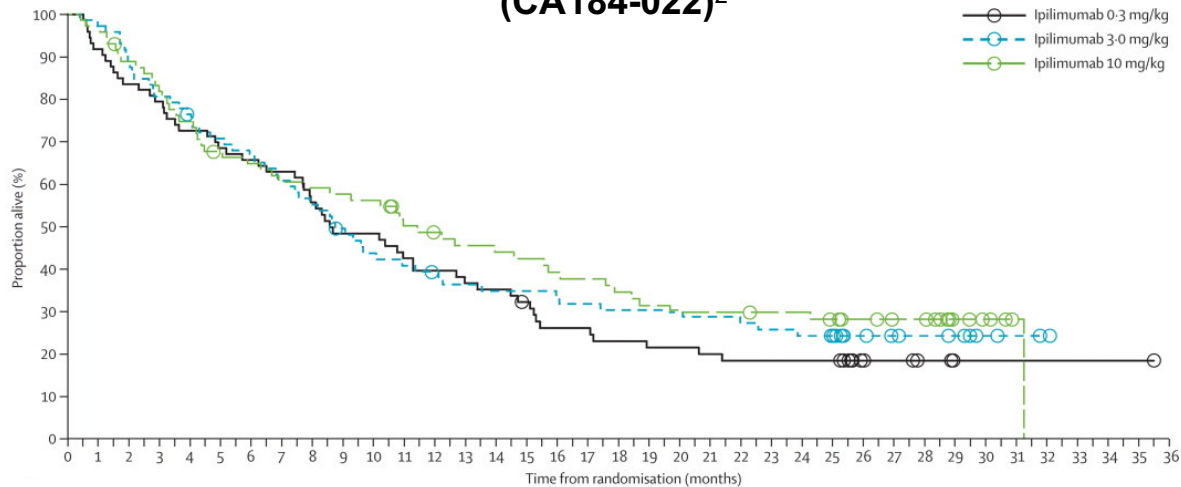
- B7/CD28 family member CTLA-4 (CD152) is constitutively expressed by TREGs but can also be upregulated by other T cell subsets, especially CD4⁺ T cells, upon activation. ⁽¹⁾
- CTLA-4 competes with CD28 for binding to CD80/CD86, although given greater binding affinity, CTLA-4 effectively diminishes signaling and mediates immunosuppression. ⁽²⁾
- CTLA-4 may also mediate immune suppression through other means including removal of CD80/CD86 on APCs via trans-endocytosis. ⁽³⁾
- Preclinically, CTLA-4 blockade elicited anti-tumor immunity with immunological memory. ⁽⁴⁾



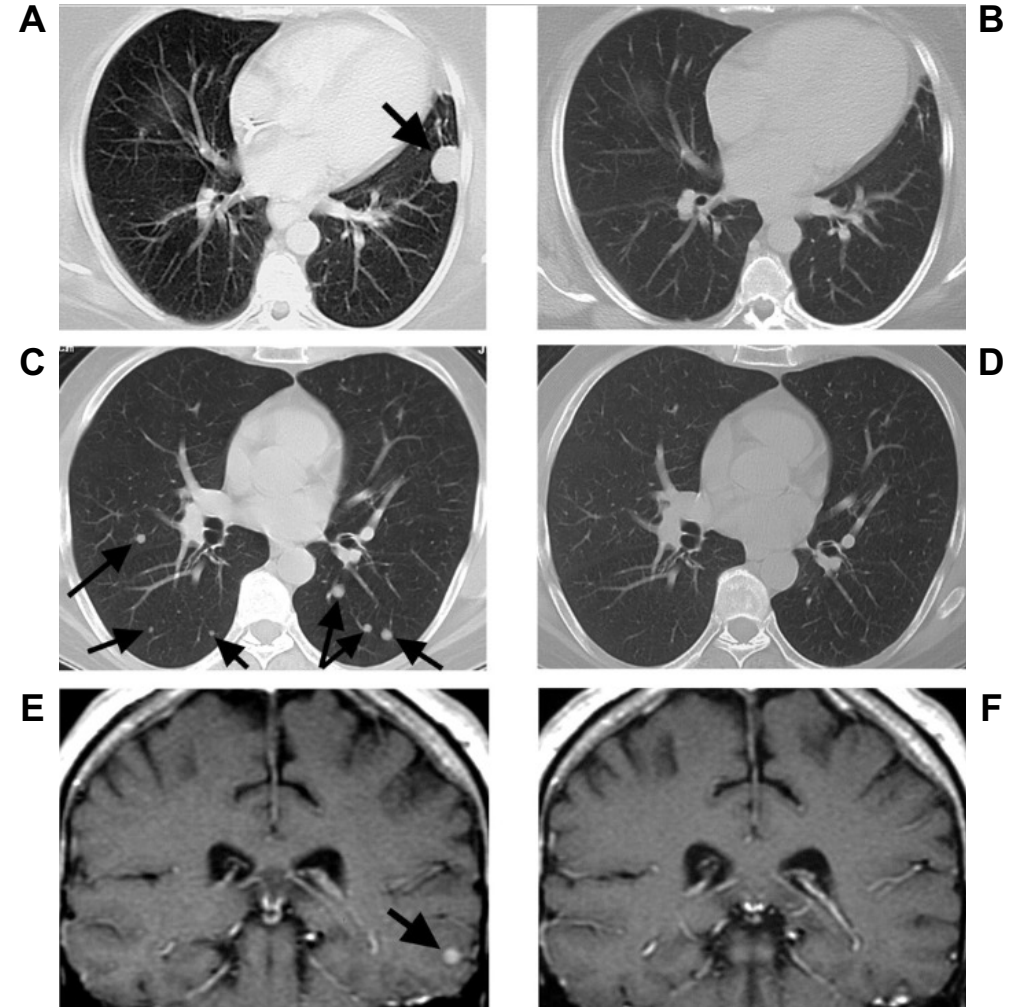
The Promise of CTLA-4 Blockade in Cancer Immunotherapy

- CTLA-4 blocking monoclonal antibody ipilimumab (MDX-010) produced durable responses in heavily pre-treated melanoma in combination with vaccine in NCI trials. ⁽¹⁾
- Randomized dose-finding trial CA184-022 confirmed doses (3mg/kg and 10mg/kg) and schedule (Q3W x4 vs. Q3W x4 + maintenance) for further development. ⁽²⁾

Randomized double-blind dose-finding study of ipilimumab (CA184-022)²

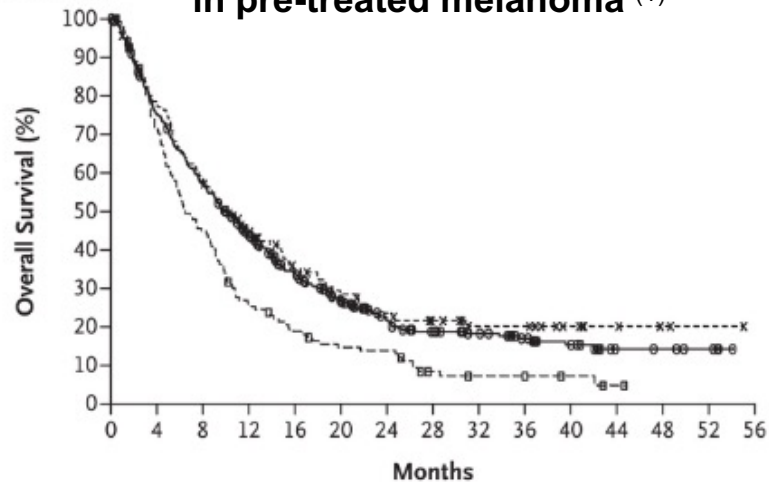


ORR: 0% (0.3mg/kg), **4.2% (3mg/kg)** and 11.1% (10mg/kg).
irAE rate: 0% (0.3mg/kg), **5% (3mg/kg)** and 18% (10mg/kg).



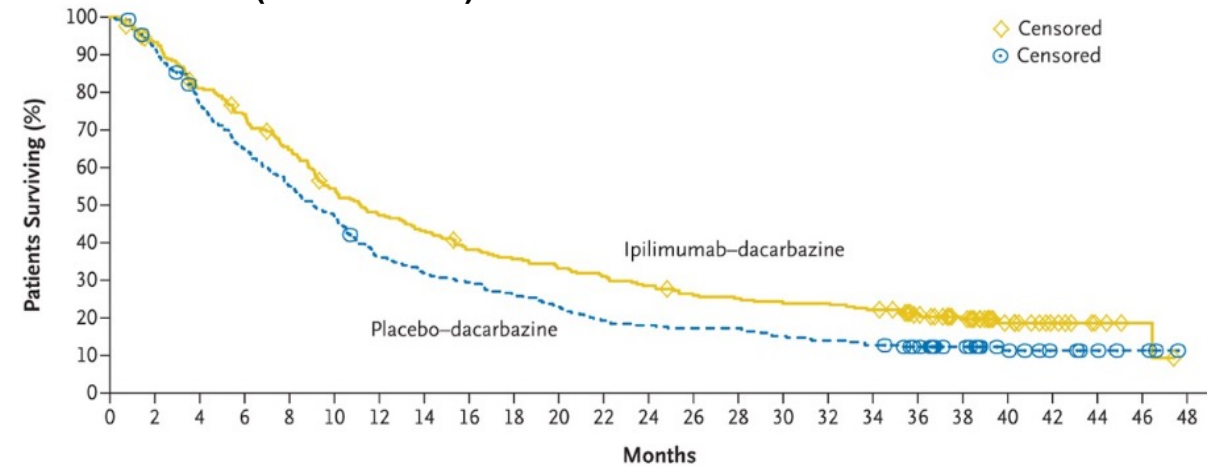
The Promise of CTLA-4 Blockade in Cancer Immunotherapy

Randomized phase 3 trial of ipilimumab +/- gp100 (MDX010-20) in pre-treated melanoma ⁽¹⁾



ORR: **11% (ipilimumab)**, 5.7% (ipilimumab+gp100), 1.5% (gp100)
2-year survival: **22% (ipilimumab)**, 24% (ipilimumab+gp100), 14% (gp100)

Randomized phase 3 trial of ipilimumab +/- dacarbazine (MDX010-24) in treatment-naïve melanoma ⁽²⁾



OS: **47% (ipilimumab+dacarbazine)**, 36% (dacarbazine)

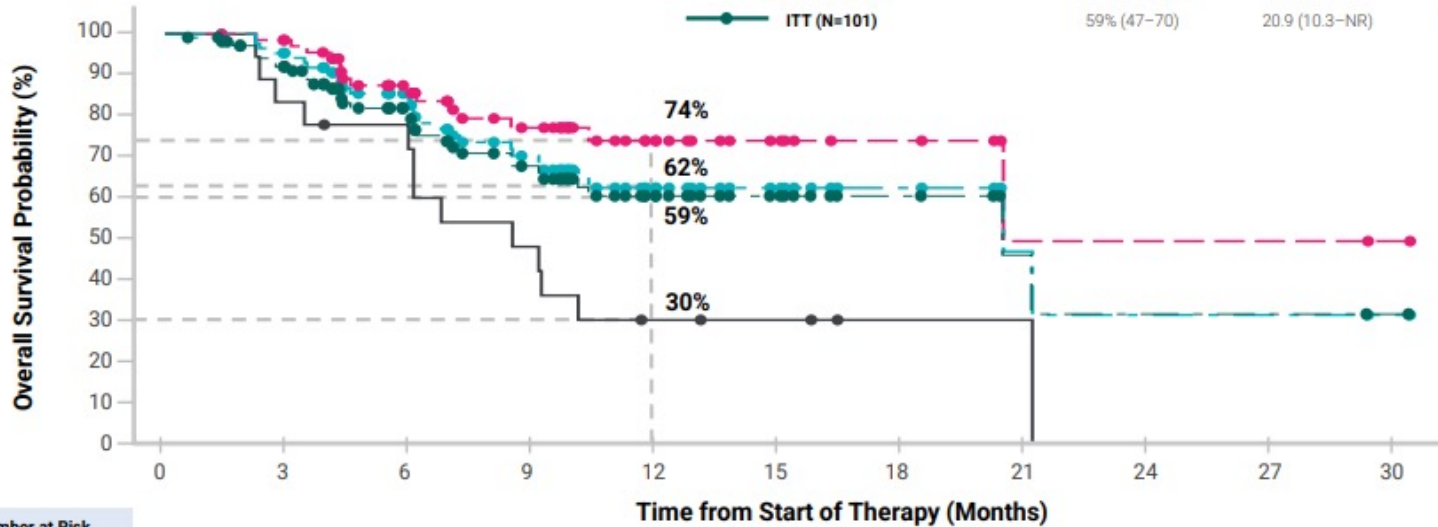
- Pivotal phase 3 studies in advanced melanoma demonstrated efficacy of CTLA-4 blockade in heavily pre-treated patients against gp100 vaccine (MDX010-020) and treatment naïve melanoma against dacarbazine (MDX010-024).⁽¹⁻²⁾
- Doses (3mg/kg -020 trial; and 10mg/kg – 024 trial) and schedules were different.

Improved Understanding of CTLA-4 Biology Results in Variants With High Binding Affinity and Improved Efficacy

Fc enhanced CTLA-4 AGEN1181 (botensilimab) binds low affinity FcγRIIIA and demonstrates clinical activity in “cold” tumors. ⁽⁵⁾

OVERALL SURVIVAL

	12-month OS, % (95% CI)	Median OS, Months (95% CI)	Median F/U, Months (Range)
No Active Liver Mets EE (n=69)	74% (59–84)	20.9 (20.9–NR)	9.8 (1.4–36.5)
Active Liver Mets EE (n=18)	30% (11–52)	8.7 (6.1–NR)	7.8 (2.3–21.7)
All EE (n=87)	62% (49–73)	20.9 (10.6–NR)	9.3 (1.4–36.5)
ITT (N=101)	59% (47–70)	20.9 (10.3–NR)	8.2 (0.5–36.5)



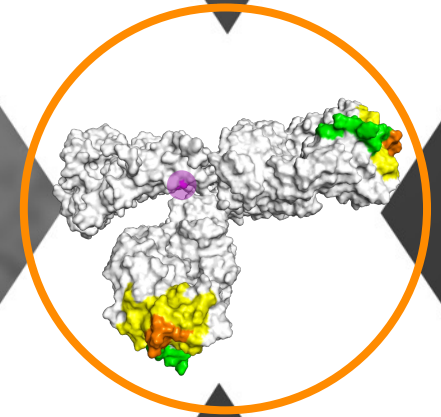
Number at Risk	0	3	6	9	12	15	18	21	24	27	30
No Active Liver Mets EE	69	65	47	33	18	11	6	2	2	2	2
Active Liver Mets EE	18	15	13	8	4	3	1	1	0	0	0
All EE	87	80	60	41	22	14	7	3	2	2	2
ITT	101	85	60	41	22	14	7	3	2	2	2

Highlights: deep durable responses in MSS CRC, significant Gr2+ irAE (particularly colitis), and lack of efficacy in liver metastases (ORR: 0%)⁽⁵⁾

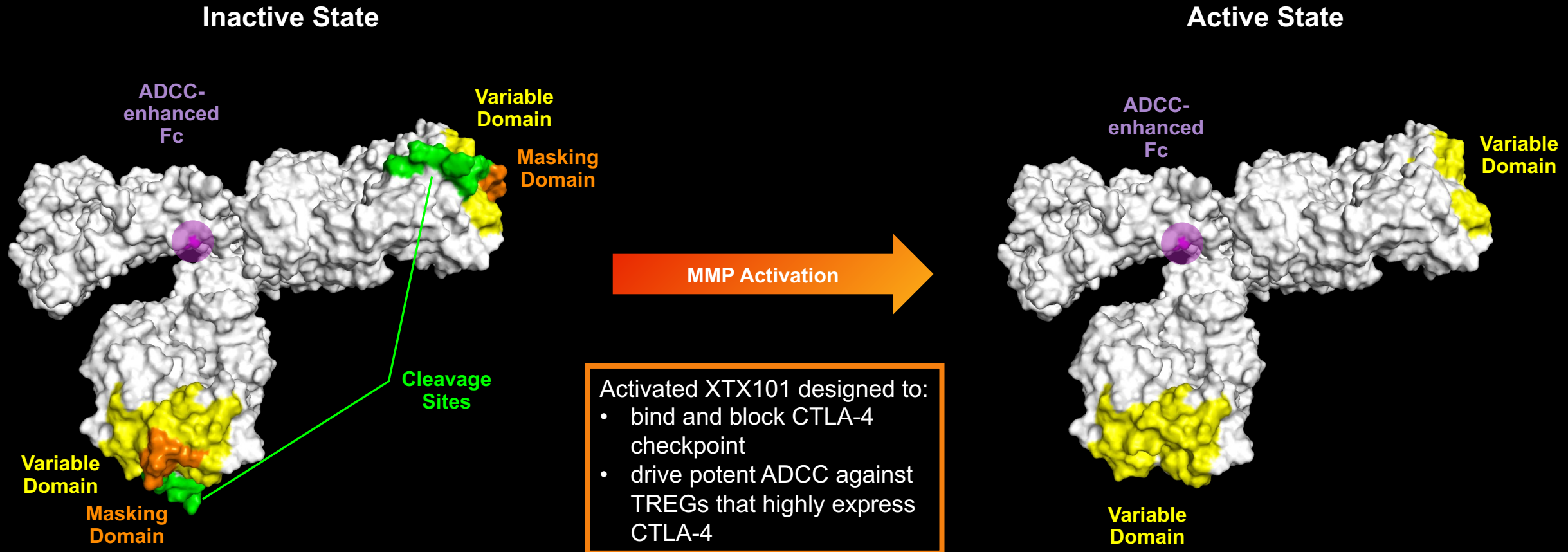
- Preclinically, TREG depletion mediated by Fcγ receptor-expressing macrophages is critical to function of CTLA-4 inhibitory mAbs. ⁽¹⁻²⁾
- Fc-FcγR interactions may also improve APC function via receptor clustering. ⁽³⁾
- Clinically, response to ipilimumab is associated with SNPs predicted to have higher binding affinity and increased ADCC. ⁽⁴⁾

XTX101

Novel, Fc-Enhanced,
Tumor-Activated Anti-CTLA-4



XTX101: Tumor-Activated, High Affinity Binding, Fc-Enhanced Anti-CTLA-4

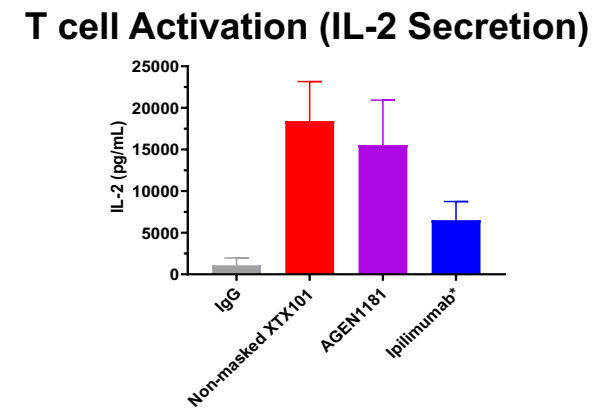
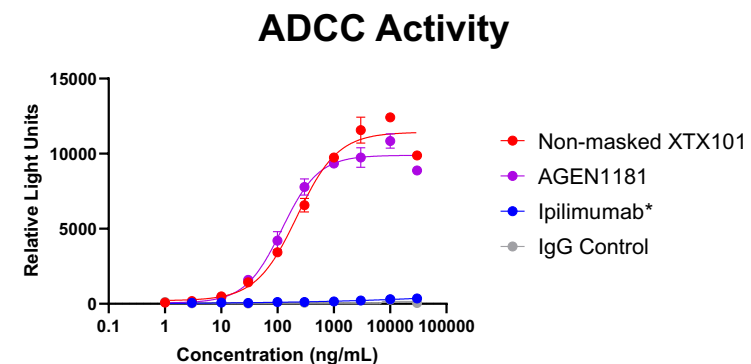
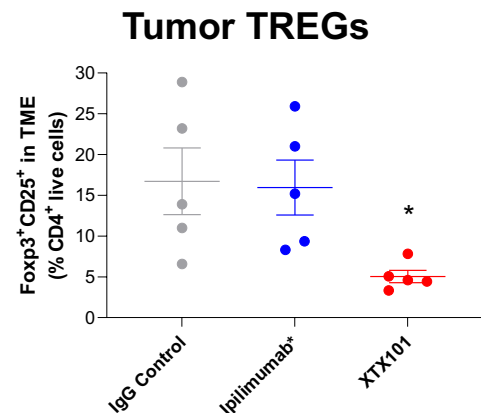
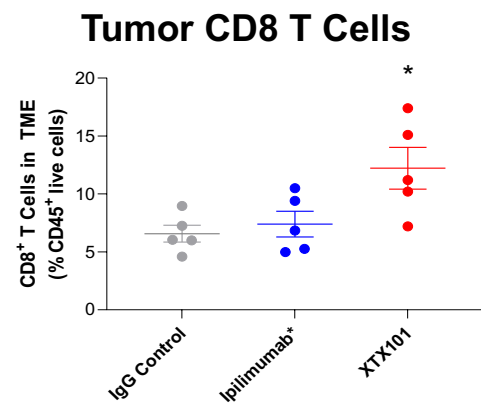
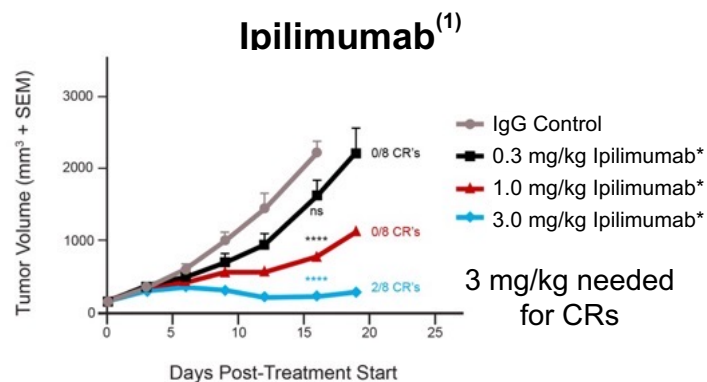
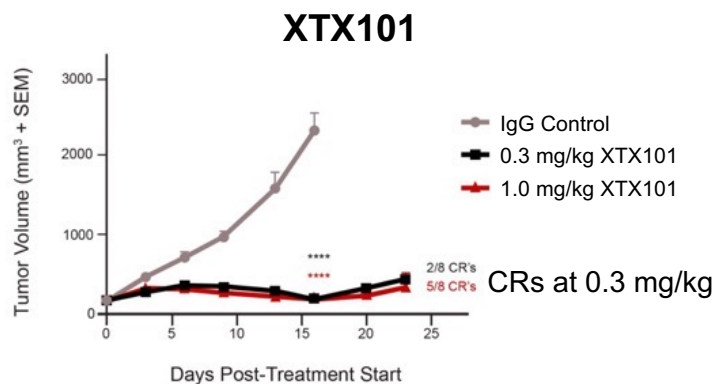


XTX101 Preclinical Profile Differentiated from Ipilimumab (10x Potency, TREG Depletion, Safety) and AGEN1181 (Safety)

XTX101 is 10-fold more potent than ipilimumab⁽¹⁾ in *in vivo* studies

XTX101 increased intra-tumoral CD8 T cells and depleted TREGs, while ipilimumab⁽¹⁾ did not

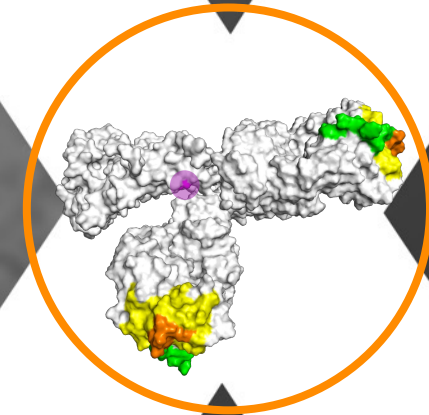
XTX101 exhibited enhanced ADCC and T cell activation vs ipilimumab⁽¹⁾ and in line with AGEN1181



1. Ipilimumab analog comprising a monoclonal antibody of identical amino acid sequence to ipilimumab that was produced at Xilio for research purposes. CR: complete regression.

Left panel: MB49 cells were inoculated subcutaneously into C57BL/6-huCTLA-4 mice. When tumors reached approximately 150 mm³, mice received a single IV dose at the doses indicated in the figure. A two-way ANOVA with Bonferroni's multiple comparisons post-test was performed to determine the statistical significance of treatment vs. isotype on Day 16 (ns: not significant; *P<0.05; **P<0.01; ***P<0.001; ****P<0.0001). **Middle panel:** MB49 cells were inoculated subcutaneously into C57BL/6-huCTLA4 mice. Mice were dosed 3 mg/kg single-dose i.v. A one-way ANOVA with Bonferroni's multiple comparisons post-test was performed to determine the statistical significance of treatment vs. isotype control IgG (*P<0.05). **Right panel:** ADCC experiment utilized reporter gene assay with human FcγRIIIa F158 (low affinity) variant. T cell activation measured in SEB (Staphylococcal enterotoxin b superantigen) assay with test articles at 100 nM concentration.

Phase 1 Clinical Trial Data for XTX101



29 Patients Enrolled in Phase 1 Trial (Phase 1A and 1B) for XTX101 with a Wide Range of Advanced and Treatment Refractory Solid Tumors

XTX101 Phase 1 Trial Design

Enrollment Completed

Phase 1A
Monotherapy Dose-Escalation
Advanced Solid Tumors
(n=20 dosed)



Phase 1B
Monotherapy Expansion PD⁽²⁾
(n=9 dosed)

Ongoing

Current dose level: 150 mg Q6W

Patient Characteristics	Total (N=27) ⁽¹⁾
Demographics	
Age, median (range)	67 (49, 80)
Female	15 (56%)
ECOG PS 0	7 (26%)
ECOG PS 1	20 (74%)
Prior Lines of Anti-Cancer Treatment	
	Median 4 (1-12)
1	2 (7%)
2	4 (15%)
3	6 (22%)
4	7 (26%)
5	3 (11%)
6 and more	5 (19%)
Prior Treatment with IO	
≥1	12 (44%)

Tumor Types	Total (N=27) ⁽¹⁾
Colorectal	6
NSCLC	4
Pancreatic	3
Squamous cell skin	2
Breast	2
Uterine	2
Merkel cell carcinoma	2
Melanoma	1
Cervical	1
Prostate	1
Gastric	1
Fallopian tube cancer	1
Leiomyosarcoma	1

Treatment Status	Total (N=27) ⁽¹⁾
Continuing on Treatment	3
Discontinued Treatment	24
Progressive Disease	14
Adverse Events	4
Consent Withdrawal (Hospice)	3
Death Due to Progressive Disease	1
Other	2

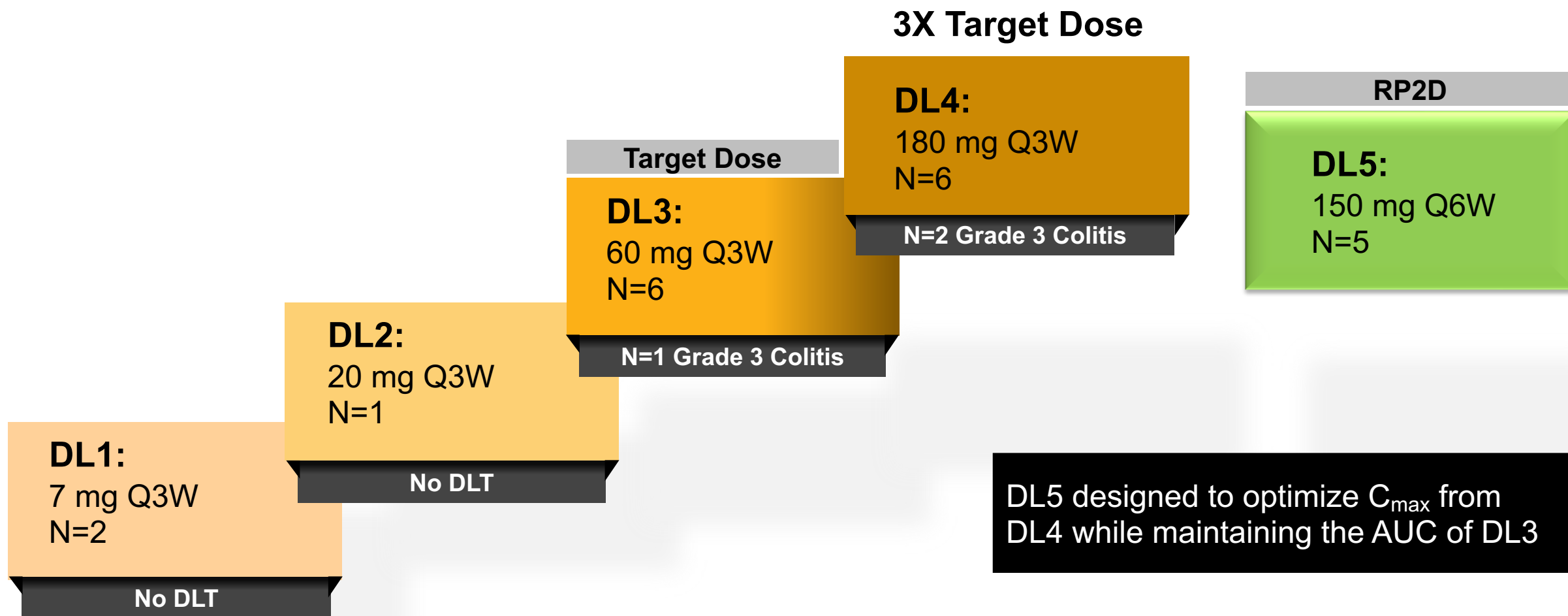
Data cutoff date: August 3, 2023. 29 patients have been dosed across all dose levels, including 20 patients dosed in Phase 1A and 9 patients dosed in Phase 1B.

1. Among the 29 patients dosed, data was not available for two patients as of the data cutoff date.

2. Eligible histology includes, but is not limited to, the following: melanoma, squamous cell skin cancer, NSCLC, head and neck squamous cell carcinoma, esophageal squamous cell carcinoma, RCC, urothelial carcinoma, MSS instability-high/mismatch repair deficient colorectal or endometrial cancer, cervical cancer, TNBC and mesothelioma.

ECOG PS: ECOG performance status; Q6W: once every six weeks; TNBC: triple-negative breast cancer

150 mg Q6W Identified as RP2D for XTX101 in Phase 1A



150 mg Q6W Identified as Optimal Dose and Schedule for XTX101

No Grade 4 or 5 AEs Observed at Any Dose Level

AE Category / Term <i>All TRAEs with ≥10% incidence in any category</i>	All Patients at Q3W (7-180 mg) (n=18)		RP2D 150 mg Q6W (n=9)	
	Any	Grade 3	Any	Grade 3
Diarrhea or Colitis	7 (39%)	4 (22%)	1 (11%)	1 (11%)
Diarrhea	5 (28%)	1 (6.0)	1 (11%)	1 (11%) ⁽¹⁾
Colitis	5 (28%)	4 (22.0)	0	0
Nausea	3 (17%)	0	0	0
Vomiting	3 (17%)	0	0	0
Abdominal pain	2 (11%)	0	0	0
Infusion related reaction ⁽²⁾	5 (28%)	3 (17%)	0	0
Fatigue	1 (6%)	0	1 (11%)	0
Decreased appetite	1 (6%)	0	1 (11%)	0
Dermatitis			1 (11%)	1 (11%)
Dose reduction due to AE		3		1
Treatment discontinuation due to TRAE ⁽³⁾		4		0

Data cutoff date: August 3, 2023. As of the data cutoff date, safety data were available for 27 patients across all dose levels, including 20 patients dosed in Phase 1A and 7 patients dosed in Phase 1B.

1. Grade 3 diarrhea with onset 10 weeks after the start of treatment (after 2 doses), resolved within 5 days without steroid use, patient tolerated 2 additional XTX101 doses after dose reduction (to 75 mg Q6W) without any symptom recurrence.

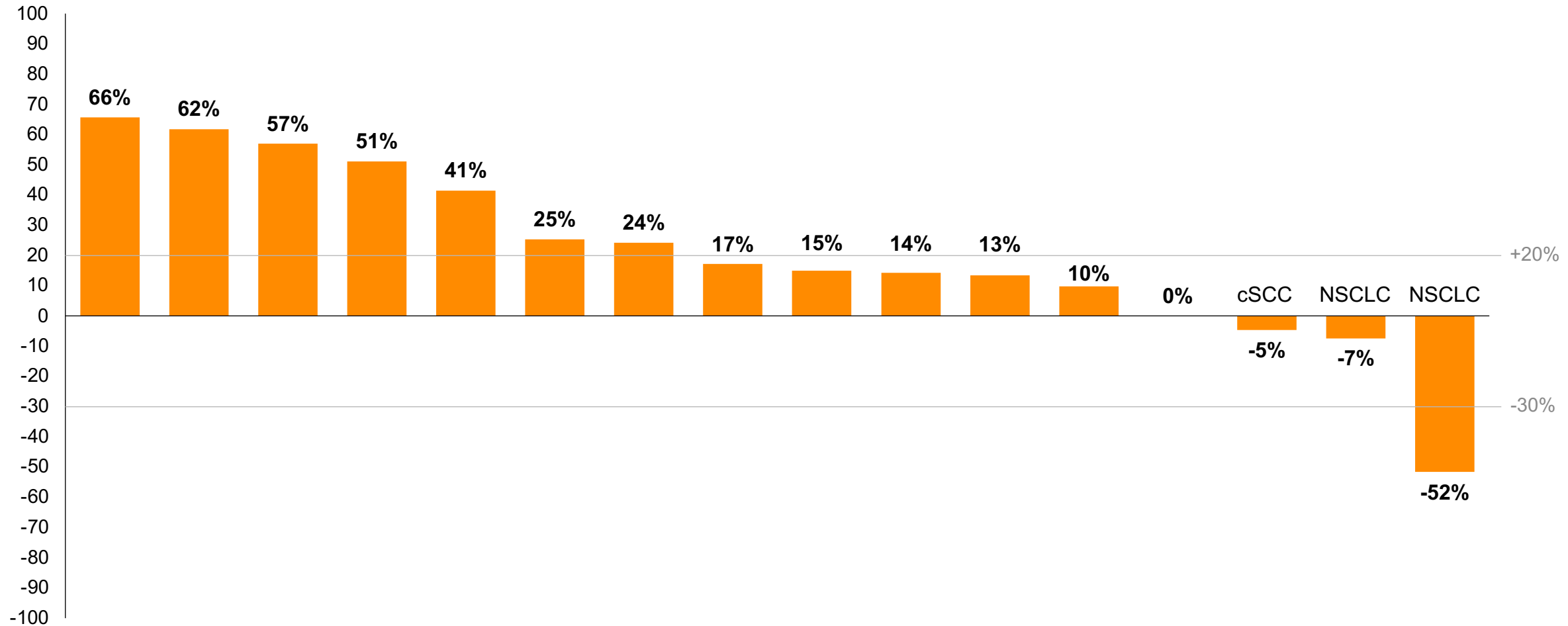
2. Infusion related reactions associated with antidrug antibodies (ADA).

3. All treatment discontinuations were due to TRAE for an infusion reaction.

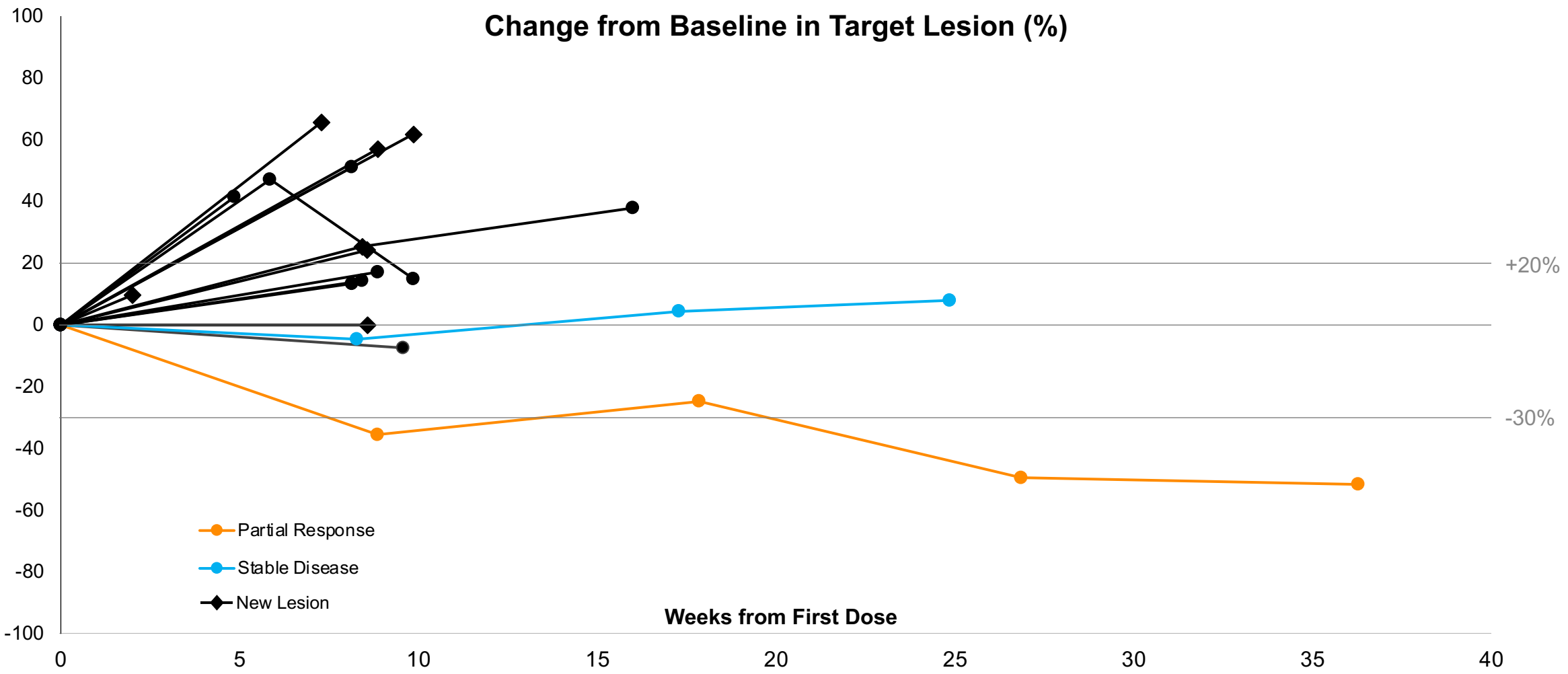
AE: adverse event; TRAE: treatment-related adverse event;

XTX101 Demonstrated Evidence of Anti-Tumor Activity in Phase 1 Trial (Phase 1A and 1B)

Best Percentage Change in Sum of Diameter from Baseline in Target Lesions (%)



XTX101 Demonstrated Prolonged Anti-Tumor Activity in a Patient with PD-L1 Negative NSCLC and Hepatic Metastases

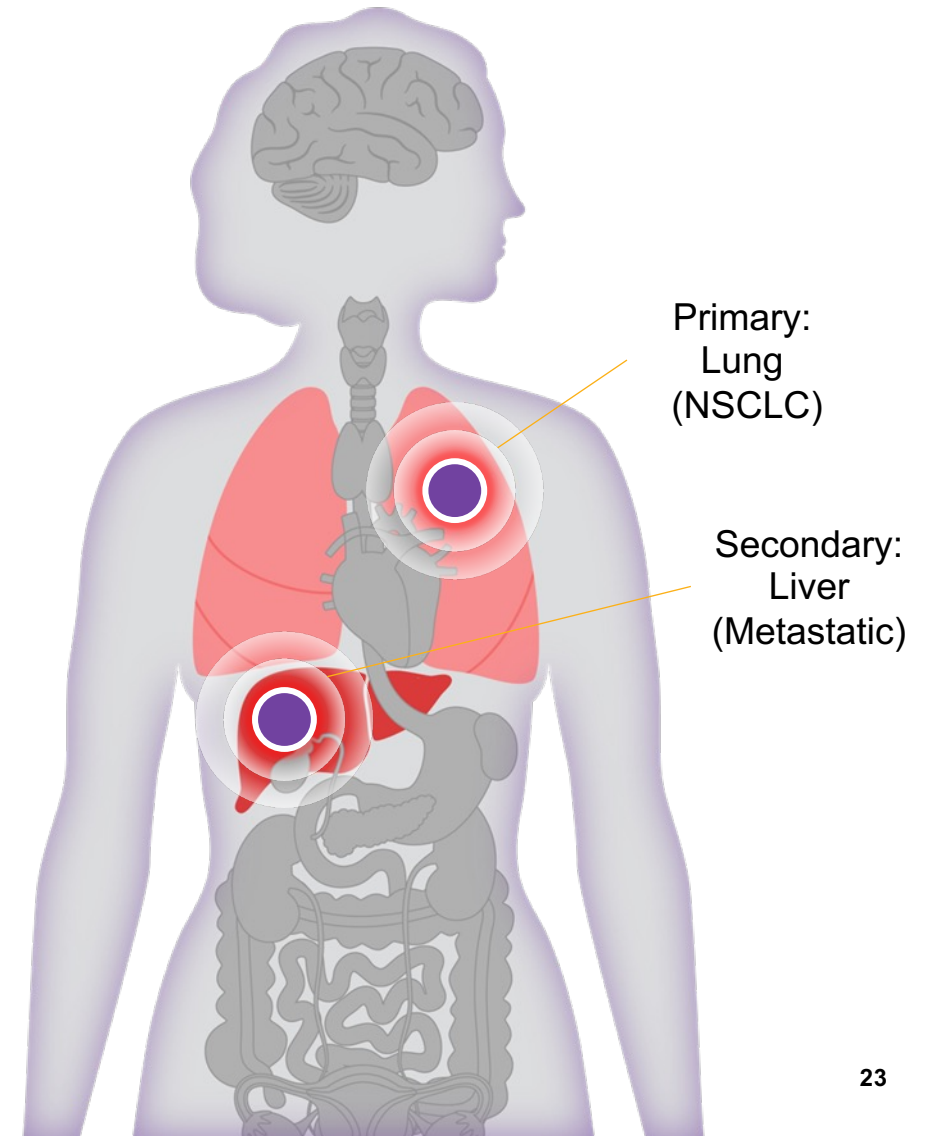


Patient Case

**Tumor-Selective Activation in a PD-L1
Negative NSCLC Patient Dosed with
XTX101 Administered at 150 mg Q6W**

XTX101 Anti-Tumor Activity in a Patient with PD-L1 Negative NSCLC and Hepatic Metastases

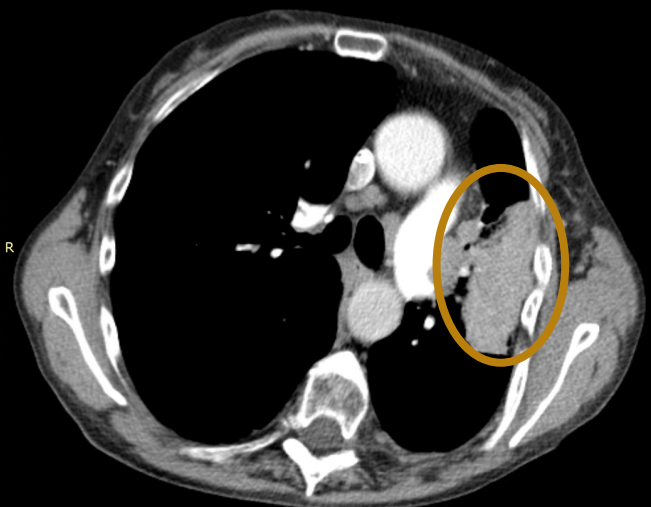
- **Patient:** 66-year-old, female
- **Diagnosis:** Stage 4 NSCLC, PD-L1 negative
- **Previous Treatment:** 1 line of chemotherapy
 - 4 cycles of paclitaxel and carboplatin
 - Complete response (CR)
 - Progressed (four months after CR)
- **Enrolled in XTX101 trial:** Cycle 1 in November 2022
- **Dose Level:** 150 mg Q6W
- **Treatment to date:** 7 doses of XTX101 administered (continuing on treatment, 36+ weeks)
- **Related AE:** Only Grade 1 fatigue



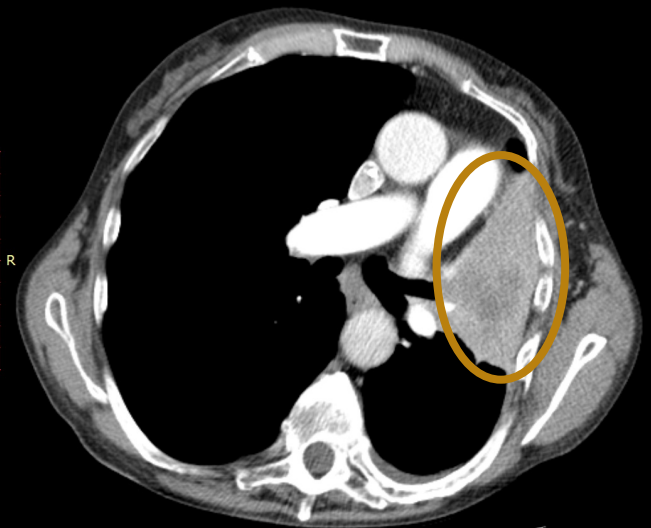
Primary Lung Lesion Decreased in Size and Developed Cavitation on XTX101 Monotherapy

Baseline

CT CHEST WWO
CHEST WITH

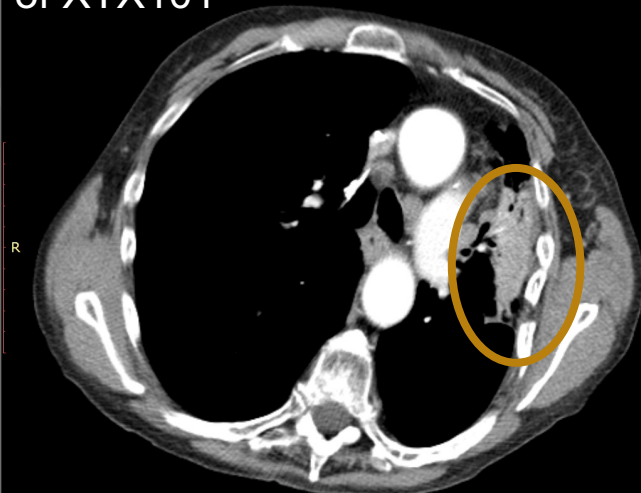


CT CHEST WWO
CHEST WITH

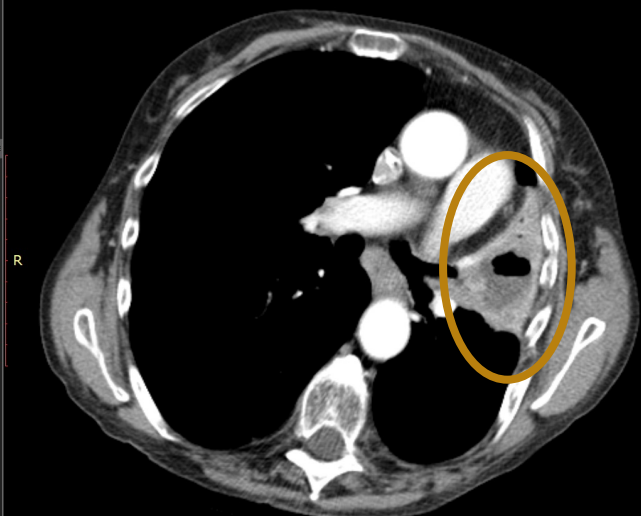


After 9 Weeks
of XTX101

CT CHEST WWO
CHEST WITH

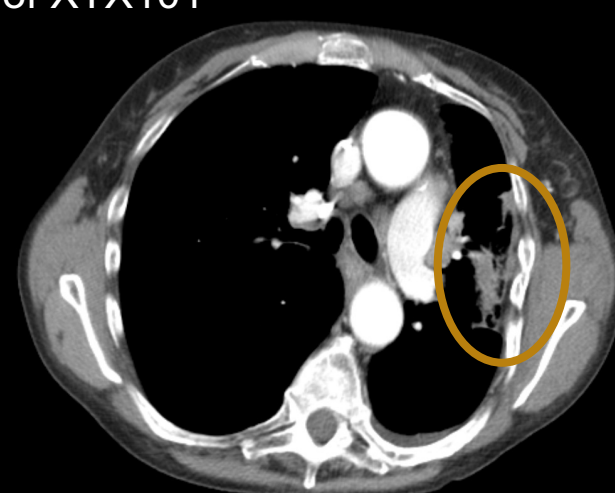


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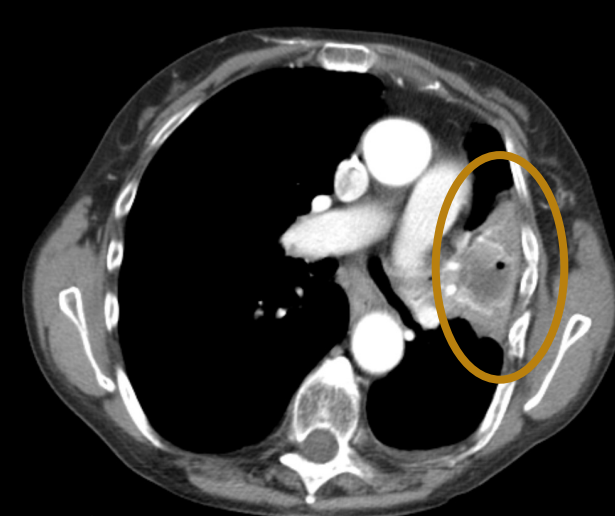


After 18 Weeks
of XTX101

CT CHEST WWO
CHEST ABD PELVIS WITH



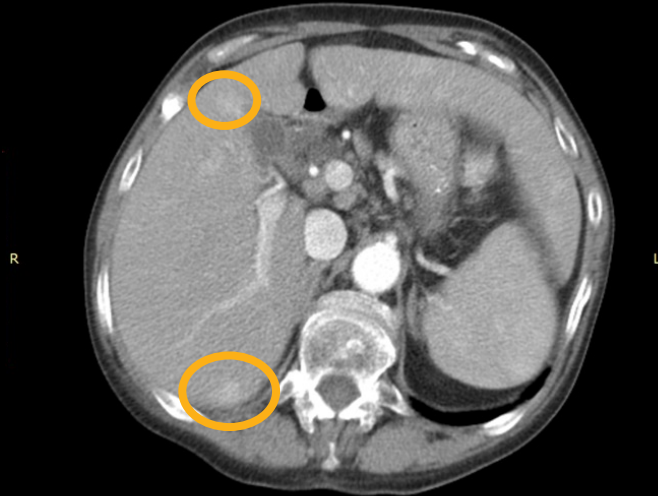
CT CHEST WWO
CHEST ABD PELVIS WITH



Hepatic Metastases Resolved on XTX101 Monotherapy

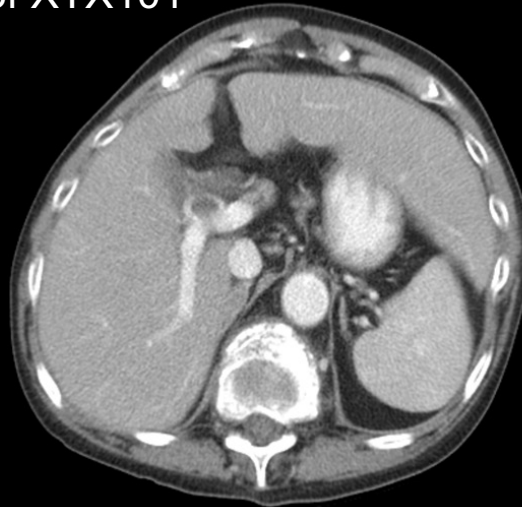
Baseline

CT ABDOMEN/PELVIS WWO
ABD PEL WITH



After 9 weeks
of XTX101

CT ABDOMEN/PELVIS WWO
ABD PEL WITH

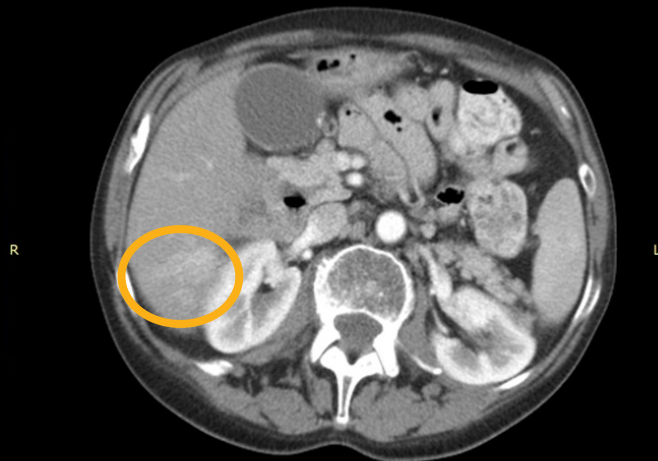


After 18 weeks
of XTX101

CT CHEST WWO
CHEST ABD PELVIS WITH



CT ABDOMEN/PELVIS WWO
ABD PEL WITH



CT ABDOMEN/PELVIS WWO
ABD PEL WITH

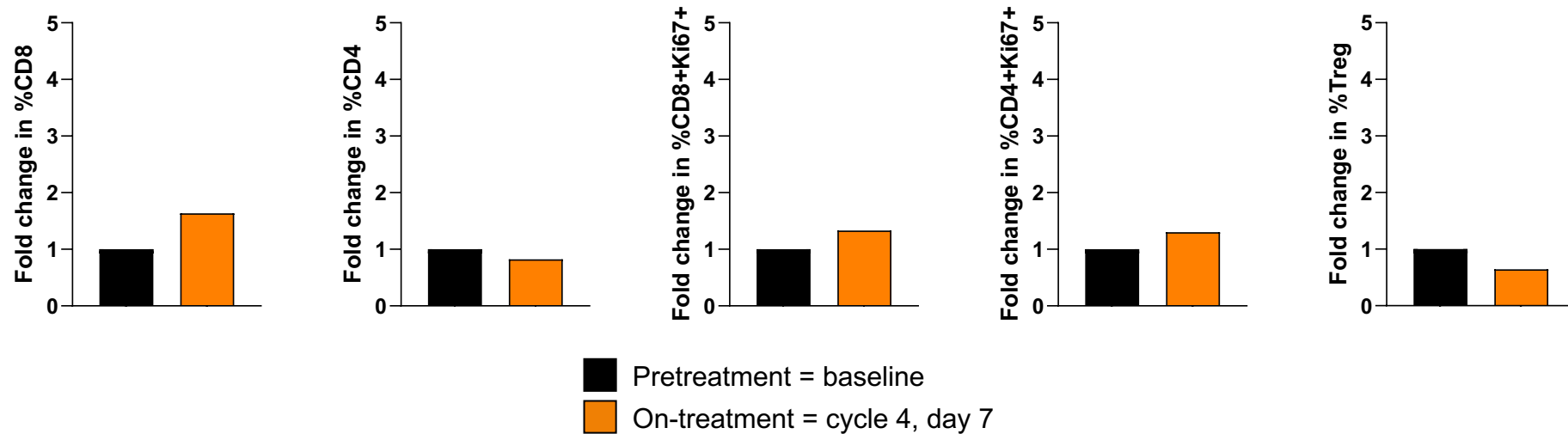


CT CHEST WWO
CHEST ABD PELVIS WITH



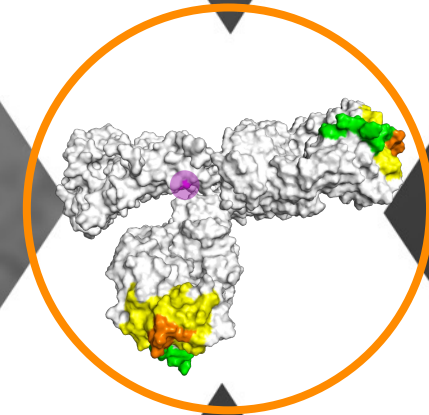
XTX101 Tumor-Selective Activity Demonstrated by Minimal Changes in Peripheral PD Markers in PD-L1 Negative NSCLC Patient with Confirmed PR

Fold Change from Baseline in Peripheral PD Markers of Anti-CTLA-4 Activity



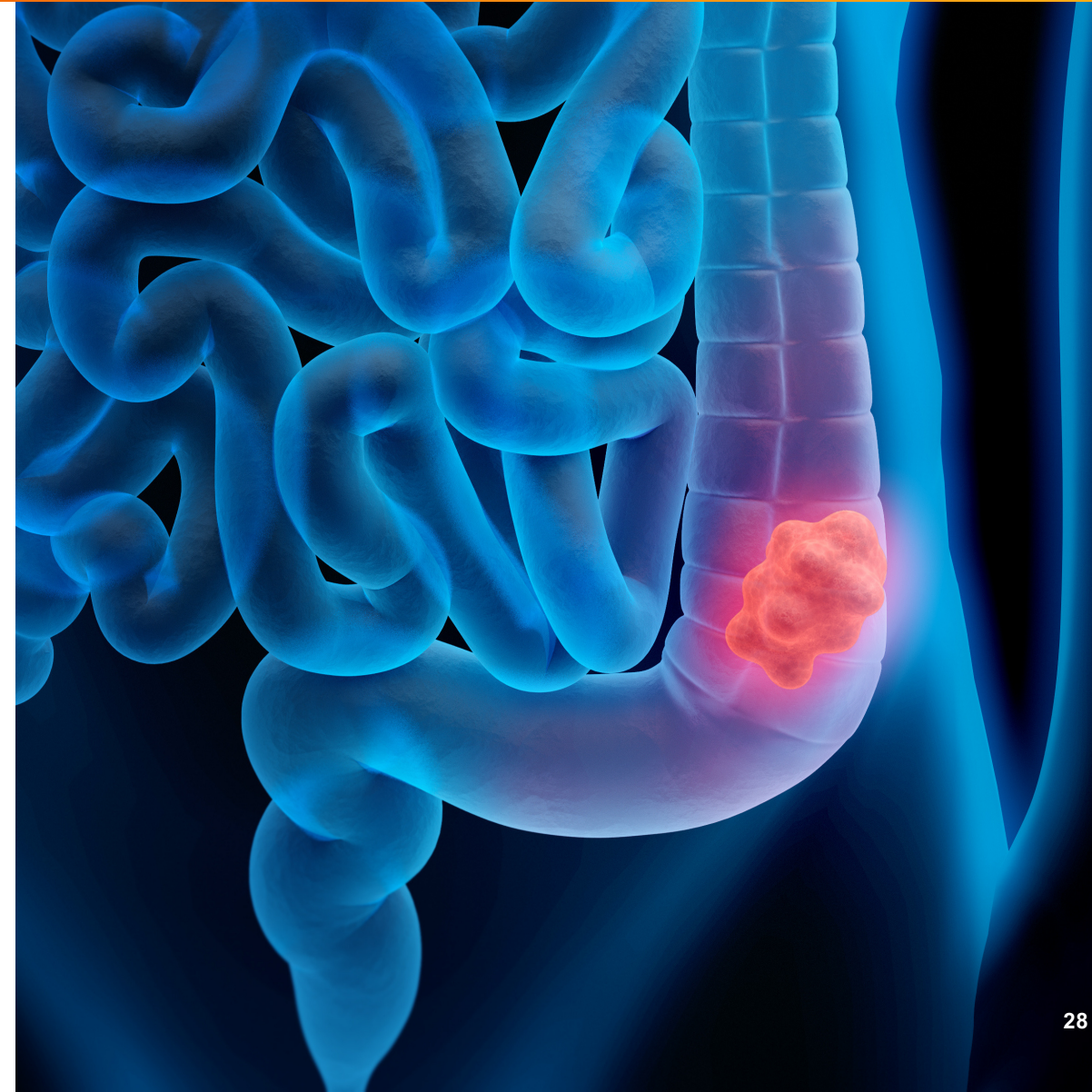
XTX101 Clinical Development Path

Pursuing XTX101 in Combination with
Atezolizumab in MSS CRC



Colorectal Cancer (CRC) – A Growing Threat to Young Adults

- In the US, colorectal cancer ranks second in cancer-related deaths overall and is the leading cause in men younger than 50 ⁽¹⁾
 - Over 150,000 patients diagnosed annually, with ~60% anticipated to have Stage 4 disease at diagnosis ⁽¹⁾
 - 52,550 CRC deaths projected in 2023, with nearly 4,000 in adults younger than 50 ⁽¹⁾
- Majority of patients diagnosed with metastatic disease (~60%) do not have surgery ⁽²⁾
 - Primary treatment approach includes chemotherapy and radiation for most patients
 - Only 2-4% of Stage 4 patients classified as MSI-H are eligible for treatment with immunotherapy, and a subset of these quickly develop immune resistance ⁽³⁾



Vast Majority of Metastatic Colorectal Cancer is MSS CRC with No Approved IO Treatment Options

~85,000 patients with Stage 4 MSS CRC in the US alone have no IO options available to treat their disease

US patients projected to be diagnosed with CRC in 2023 ⁽¹⁾ **~150,000**

~60% of patients will be diagnosed with Stage 4 disease ⁽¹⁾ **~90,000**

~95% of Stage 4 disease is MSS CRC ⁽²⁾ **~85,000**

~70% of patients with Stage 4 disease develop liver metastases ⁽⁶⁾ **~60,000**

- MSS CRC represents the vast majority of metastatic CRC (95%) ⁽²⁾
 - Characterized by tumors with weak immunogenicity and limited immune cells (making it a “cold tumor”)
 - Checkpoint inhibitors ineffective in MSS CRC to date ⁽³⁾
 - PD-1 monotherapy: ORR 0% (n=150)
 - Ipilimumab + nivolumab: ORR 5% (n=20)
 - Opportunity exists for IO combinations that together can help mount an adequate immune response
- Liver is most common site of metastases in CRC ⁽⁵⁾
 - Over 80% of patients with liver metastases from CRC have unresectable lesions ⁽⁵⁾
 - Long-term survival remains rare, with these patients often excluded from clinical trials, particularly for IO

1. Siegel et al, Colorectal Cancer Statistics, (2023).

2. Ooki et al, Journal of Anus Rectum Colon, (2021).

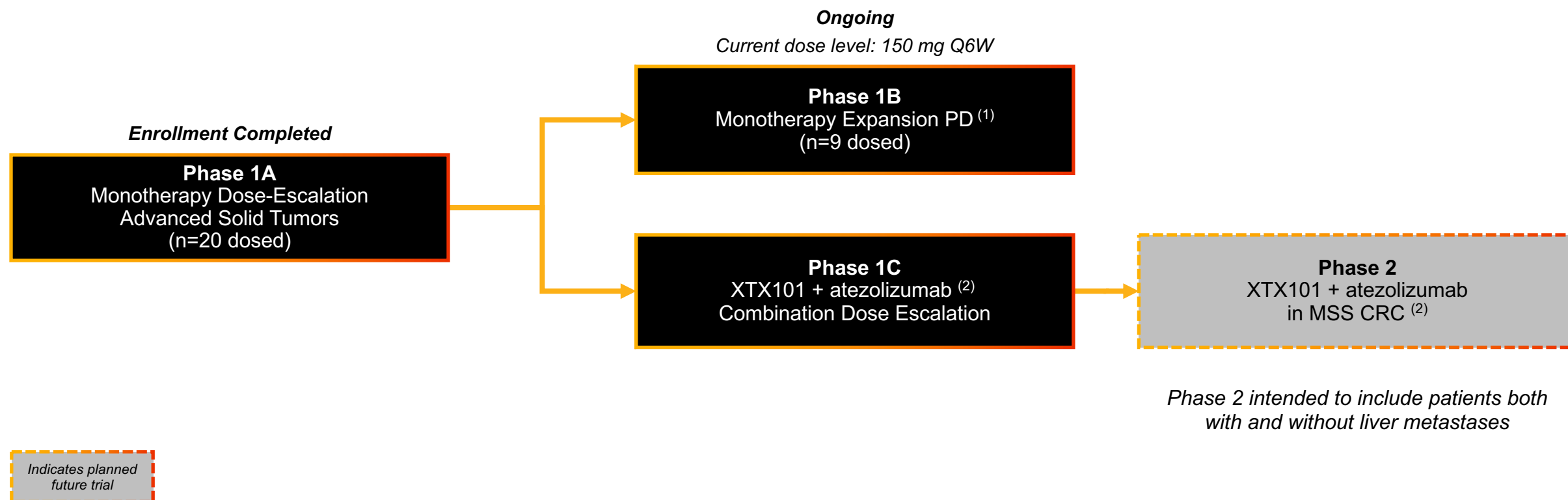
3. Bullock AJ, Grossman JE, Fakih MG, et al: ESMO World Congress on Gastrointestinal Cancer 2022. Abstract LBA-09. Presented June 29, 2022.

4. Valderrama-Trevino et al, EJOHG, (2017).

5. Sheth et al, Clinics in Colon and Rectal Surgery (2005).

6. Cerner Enviza, (2023).

Clinical Development Plan for XTX101



Plan to activate clinical trial sites for combination dose escalation to evaluate XTX101 in combination with atezolizumab in Q4 2023

XTX101 Clinical Trial Progress and Anticipated Milestones



- RP2D defined at 150 mg Q6W with differentiated safety profile
- Preliminary PK analyses demonstrated dose-proportional drug exposure and limited active (unmasked) molecule in the periphery
- 150 mg dose provided a 2x higher C_{max} (adjusted for 10x higher potency) compared to ipilimumab 10 mg/kg
- Monotherapy confirmed partial response in a patient with PD-L1 negative NSCLC reported at 150 mg Q6W with resolution of hepatic metastases ⁽¹⁾
 - Tumor-selective activation for XTX101 demonstrated by minimal peripheral PD in this patient



- Anticipate activating clinical trial sites for Phase 1 dose escalation evaluating XTX101 in combination with atezolizumab in Q4 2023

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Xilio would like to thank the patients participating in our clinical trials, as well as their families and caregivers.

We are humbled by their commitment and support in bringing us closer to achieving our mission to design and deliver tumor-activated immuno-oncology therapies that provide effective, tolerable and durable therapeutic options for patients with solid tumors.

Q&A

Spotlight on XTX101: a Novel, Fc-Enhanced, Tumor-Activated anti-CTLA-4

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