RAPT THERAPEUTICS

FLX475 (Tivumecirnon): Oral CCR4 Antagonist with Clinical Activity in Cancer

November 3, 2023

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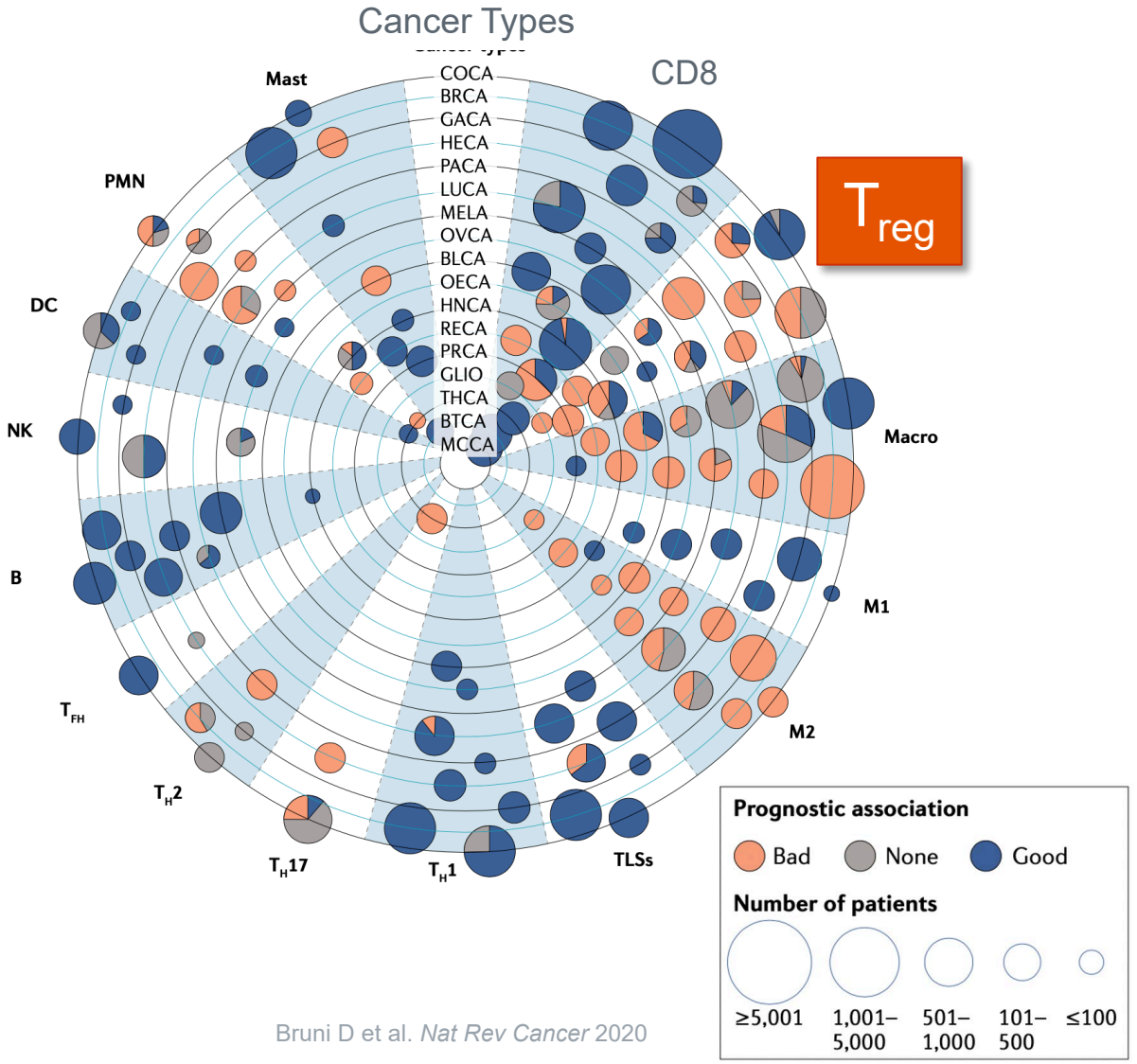
Executive Summary

- FLX475 (tivumecirnon), a selective oral CCR4 antagonist, has shown encouraging monotherapy and combination activity with anti-PD-1 (pembrolizumab) in T_{reg}-enriched cancers
- In a Phase 2 cohort in CPI-naïve NSCLC, FLX475/pembrolizumab showed encouraging clinical efficacy relative to historical pembro monotherapy*
  - **40%** confirmed ORR in PD-L1+ (TPS ≥1%) vs. **18%** with pembro mono
    - **38%** confirmed ORR in PD-L1 low (TPS 1-49%) vs. **10%** with pembro mono
    - **50%** confirmed ORR in PD-L1 high (TPS ≥50%) vs. **30%** with pembro mono
  - **6.3 mo** median PFS in PD-L1+ vs**. 4 mo** with pembro mono
- Favorable safety profile with potential for broad combinability with other agents

* Cutoff date Oct. 6, 2023; 11 patients remain on treatment; historical pembrolizumab monotherapy data from KEYNOTE-010 and KEYNOTE-001

T_{reg} Are Key Targets in the Tumor Microenvironment (TME)

- Potent suppressors of effector T cells and antigen presenting cells
- Correlate with poor prognosis across most cancers
- Mechanism for immune evasion by viruses and tumors
- Barrier to checkpoint inhibitor efficacy
- **Challenge**: <u>selective</u> inhibition of T_{reg} <u>specifically</u> in the tumor



Bruni D et al. *Nat Rev Cancer* 2020

FLX475 Advantages: Selective Inhibition of Tumor T_{reg}

Traditional Approach: Depleting Antibodies

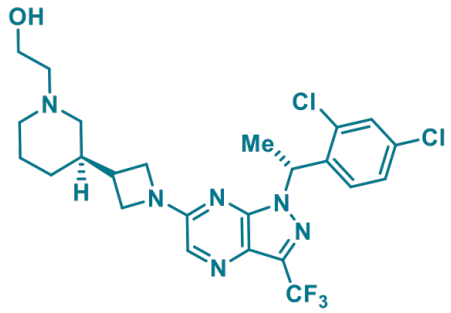
Examples: anti-CD25, anti-CCR4, anti-CCR8

ADCC-mediated T_{reg} depletion

POTENTIAL ISSUES

- ! Systemic depletion of T_{reg} = **increases toxicity**
- ! Poor/variable T_{reg} depletion in the tumor = **reduces efficacy**
- ! Nonspecific depletion of antitumor T cells = **reduces efficacy**

RAPT's Solution: **FLX475**



Blocks **tumor-specific** T_{reg} trafficking

ADVANTAGES

- ⊕ Specific reduction of tumor T_{reg} = **reduces toxicity**
- ⊕ Robust reduction of tumor T_{reg} = **increases efficacy**
- ⊕ No depletion of antitumor T cells = **increases efficacy**

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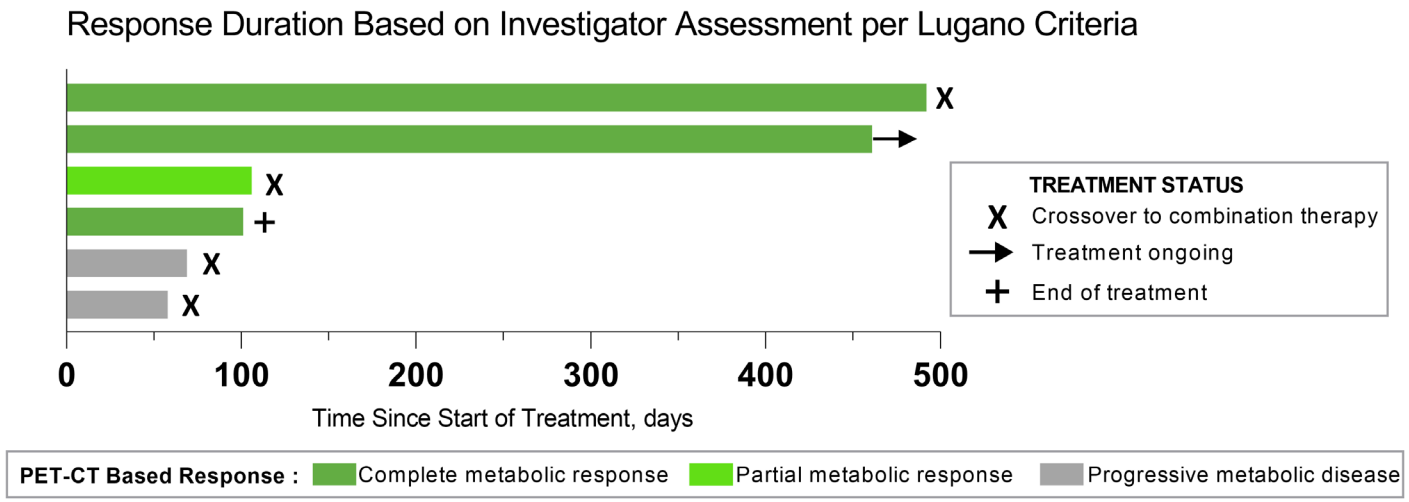
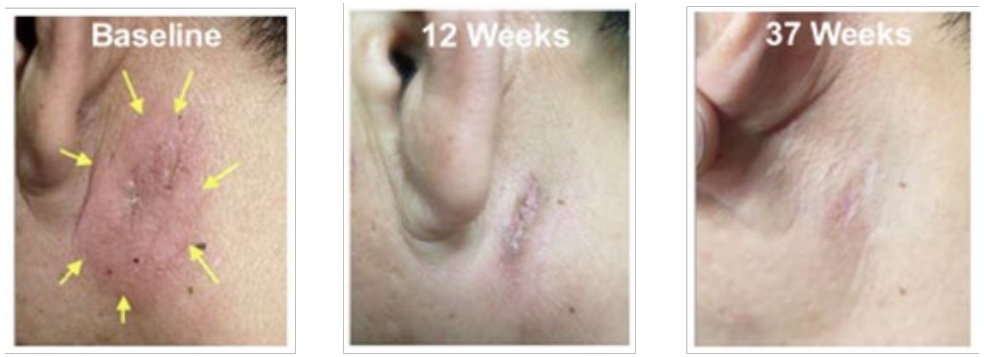
FLX475 Shows Encouraging Efficacy as Monotherapy and in Combination with Pembrolizumab

EBV+ NK/T Lymphoma (Mono)

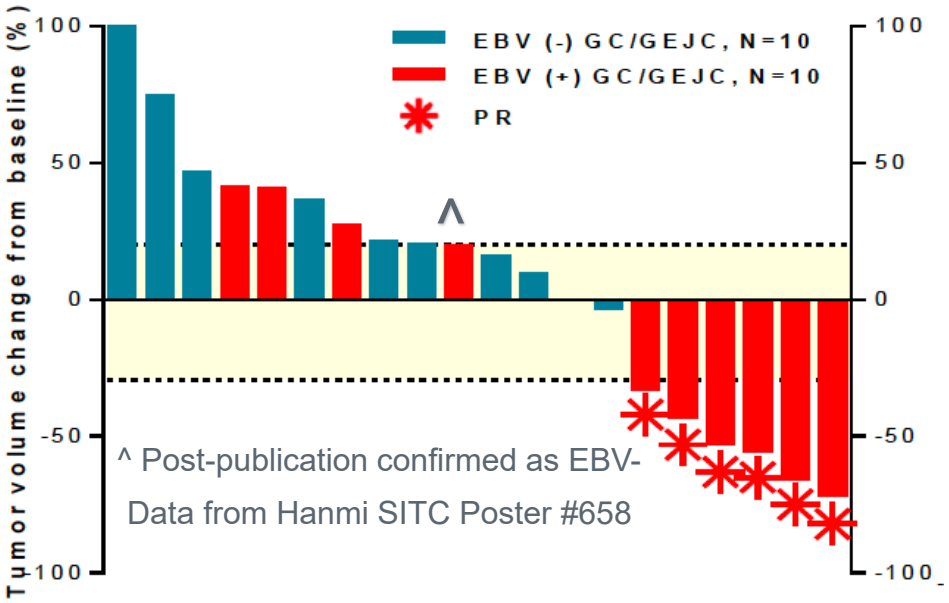


- **4 of 6 responses including 2 confirmed durable complete metabolic responses**
- **Resolution of visible target lesion in 1st subject above**



(Lin C.-C. et al ESMO-IO 2022 Dec; #187P)

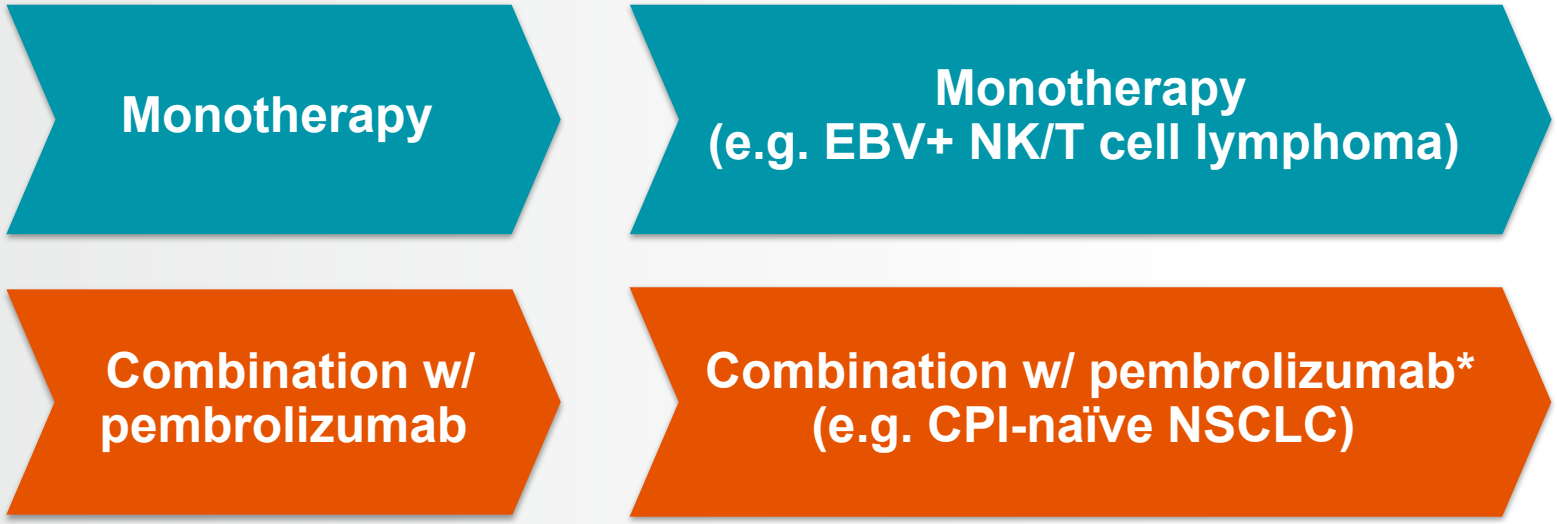
EBV+ Gastric Cancer (Combo)



- **Ph2 Study run by Hanmi in S. Korea**
- **6/9* (67%) confirmed PRs (one later evolved to CR)**
- **In aggregate, trials with anti-PD-(L)1 therapy alone showed a ~33% ORR**

FLX475 Phase 2 Clinical Development

Tumor types selected based on **T_{reg}- and CCR4 ligand-enrichment** and studied in individual cohorts



- **Design**: Open-label Phase 2, Simon 2-Stage Design
- **Treatment**: FLX475 100 mg QD; pembrolizumab 200 mg Q3 wk (for up to 2 years)
- **Primary Phase 2 Endpoint:** Objective Response Rate

* Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA is providing pembrolizumab for the study

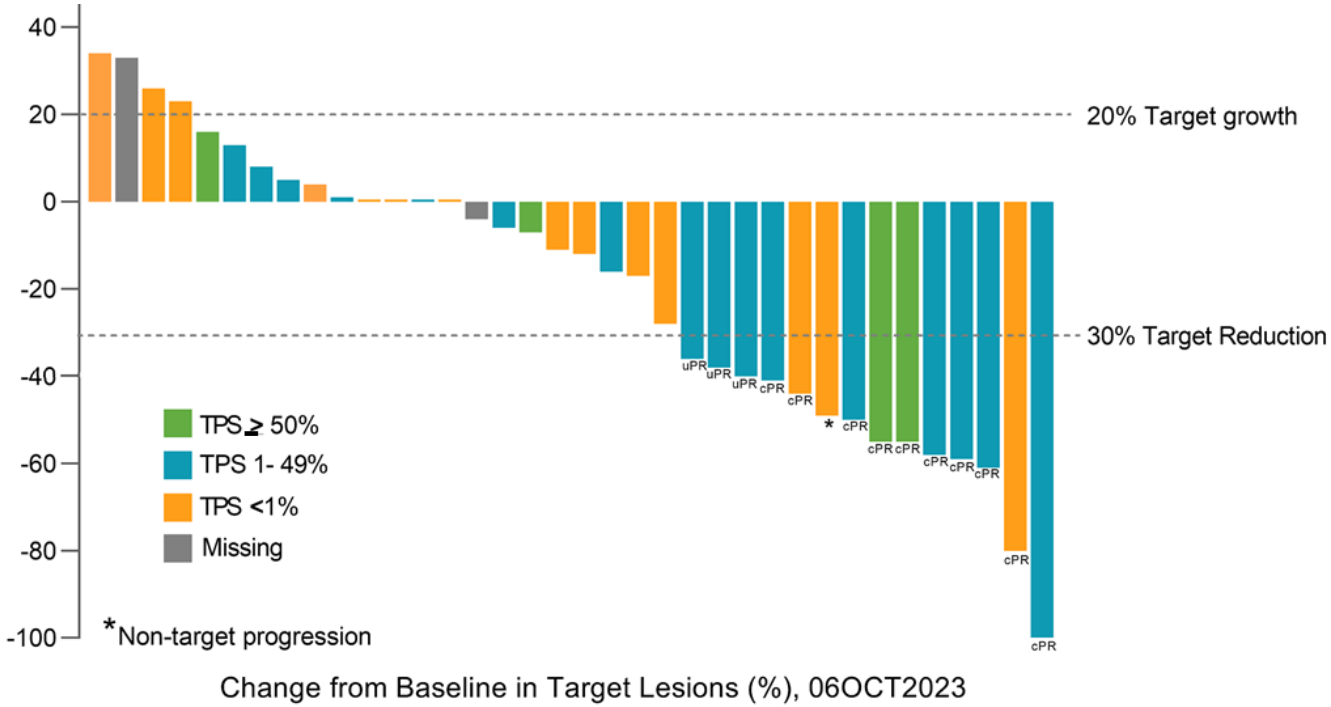
Phase 2 Stage 1 and 2 CPI-Naïve NSCLC Baseline Characteristics

	All CPI-Naive (N = 36)	PD-L1+ (N = 20)
Age, mean (range), years	69 (47-87)	67 (58-87)
Male, n (%)	29 (81%)	15 (75%)
ECOG PS, n (%)		
0	8 (22%)	4 (20%)
1	28 (78%)	16 (80%)
Previous Lines of Therapy for Advanced Disease, n (%)		
0	10 (28%)	7 (35%)
1	13 (36%)	7 (35%)
2	6 (17%)	2 (10%)
3+	7 (19%)	4 (20%)
Histology, n (%)		
Squamous	16 (44%)	9 (45%)
Non-squamous	20 (56%)	11 (55%)
PD-L1 Status*, n (%)		
TPS <1%	14 (39%)	--
TPS ≥1%	20 (56%)	20 (100%)
TPS 1-49% / TPS ≥50%	--	16 (80%) / 4 (20%)
Unknown	2 (5%)	--

- N=36 efficacy-evaluable subjects in Stages 1 and 2
- N=20 PD-L1+ (TPS ≥ 1%)
  - Majority are previously treated (65%) and PD-L1 low (80%)
- Median follow-up of 250 days
- Data cutoff: October 6, 2023

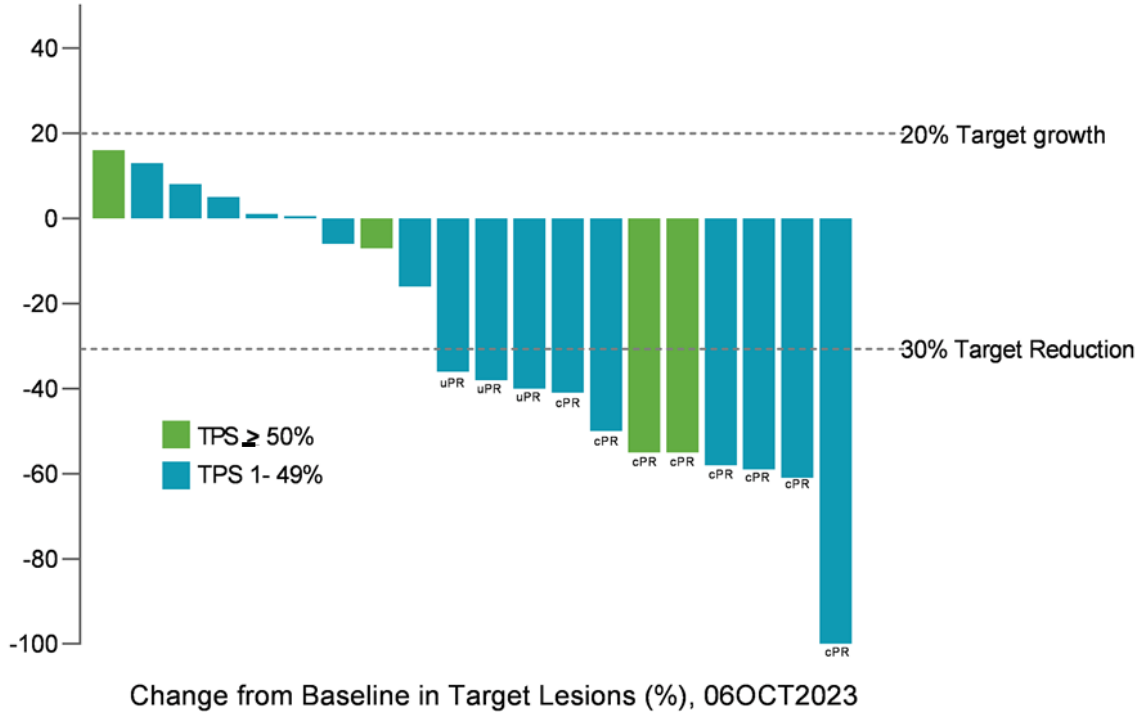
Positive Phase 2 Clinical Efficacy in CPI-Naïve NSCLC

BOR All Evaluable (n=36)



- Overall confirmed ORR: 28% (10/36), regardless of PD-L1 status

BOR PD-L1+ (n=20)

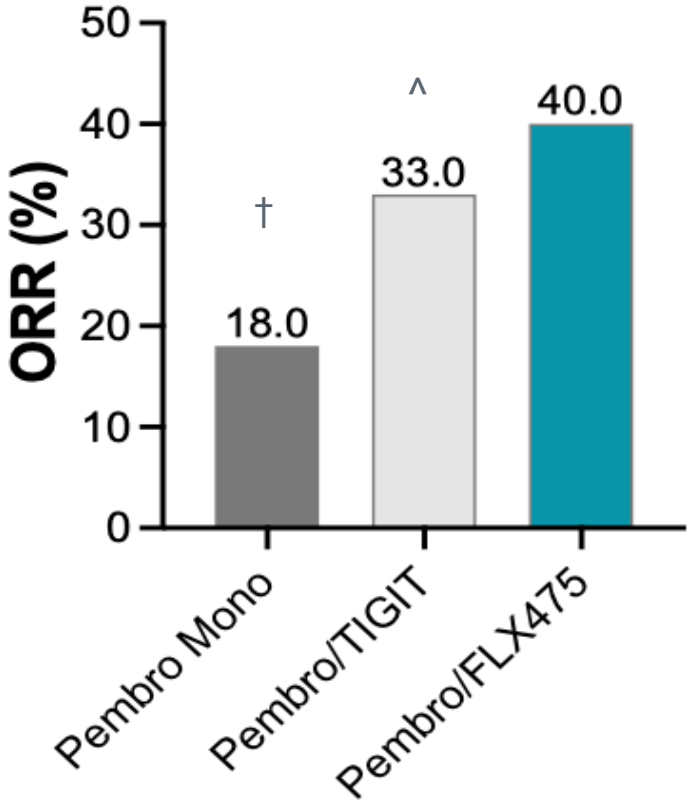


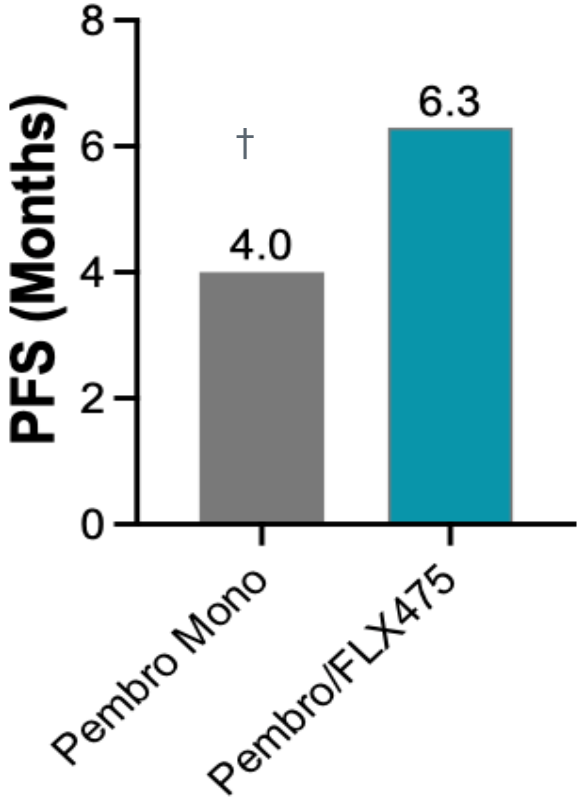
- **PD-L1+ confirmed ORR = 40% (8/20)**
  - Additional uPR pending confirmation
- **PD-L1+ median PFS = 6.3 mo**
- **Data expected to mature/improve**

BOR = Best Overall Response

FLX475/Pembrolizumab Efficacy in CPI-naïve NSCLC Exceeds Historical CPI Data

Efficacy Data in **PD-L1+*** NSCLC
(Previously Treated or Mixed)





*TPS ≥ 1%; †ORR and PFS from Keynote-010 (previously treated);
^Niu et al. Ann. Onc. 2022 (mixed 1L and 2L+)

Cross trial comparisons;
Data do not represent randomized comparisons

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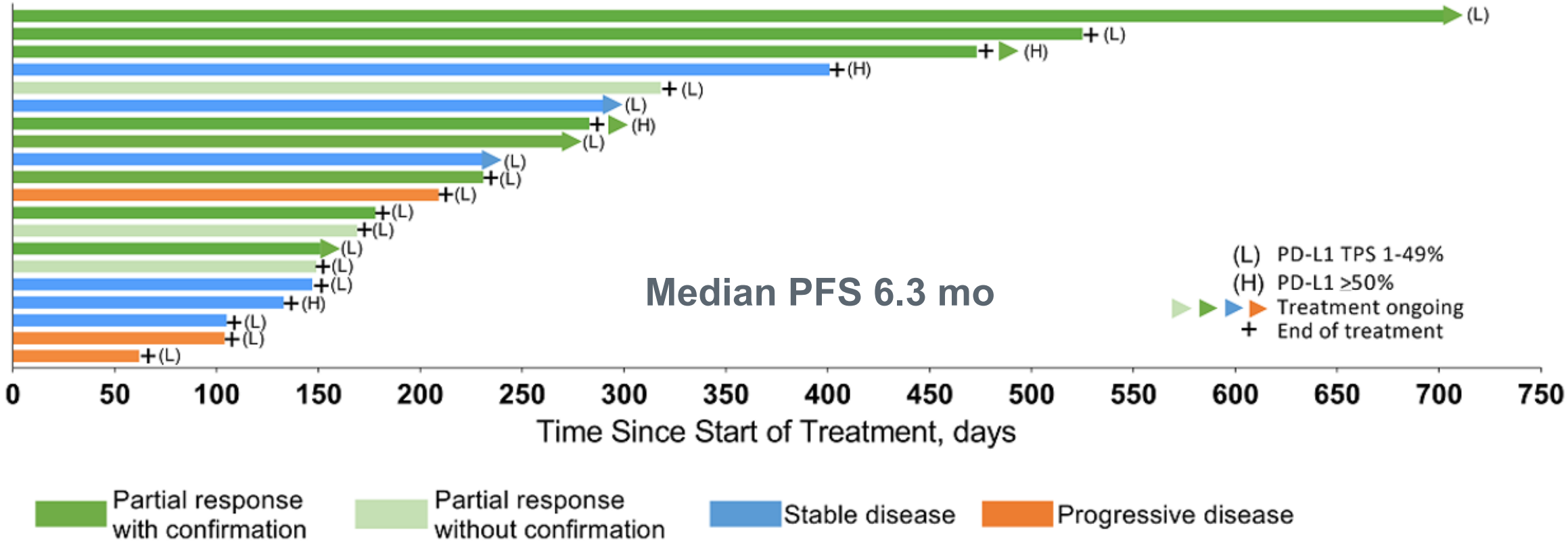
Duration on Treatment for PD-L1+ CPI-Naïve NSCLC



- As of 06OCT2023 cutoff:
  - Median duration of follow-up 8.3 months
  - 7/20 PD-L1+ subjects still on treatment
    - Median duration of treatment: 220 days (62-703)

FLX475/Pembrolizumab Efficacy Not Limited to PD-L1 High

- Efficacy by CPI-naïve NSCLC subgroup (confirmed responses)
  - PD-L1+ (TPS ≥1%): **40% ORR** (8/20)
  - PD-L1 low (TPS 1-49%): **38% ORR** (6/16)
  - PD-L1 high (TPS ≥50%): **50% ORR** (2/4)

	FLX475 + Pembrolizumab (N=36)	
By PD-L1 Status	With Confirmation^	Without Confirmation
TPS ≥1%: responders; ORR % (95% CI) (all PRs)	8/20; 40% (22-61%)	11*/20; 55% (34-74%)
Median PFS, months (95% CI)	6.3 (3.4-NR)	--
Median DoR, months (range)	10.2 (2-20.6+)	--
TPS 1-49%: responders; ORR % (95% CI)	6/16; 38% (18-61%)	9*/16, 56% (33-77%)
TPS ≥50%: responders; ORR % (95% CI)	2/4; 50% (15-85%)	2/4; 50% (15-85%)
TPS <1%: responders; ORR % (95% CI)	2/14; 14% (3-42%)	2/14; 14% (3-42%)

ORR: Overall Response Rate; PR: Partial Response
PFS: Progression-free Survival; DoR: Duration of Response: NR: Not Reached
^Response confirmation per RECIST v1.1
*Includes 1uPR awaiting confirmatory scan results
Data cutoff 06OCT2023; median duration of follow-up 8.3 months (0.3 - 29.4 mo)

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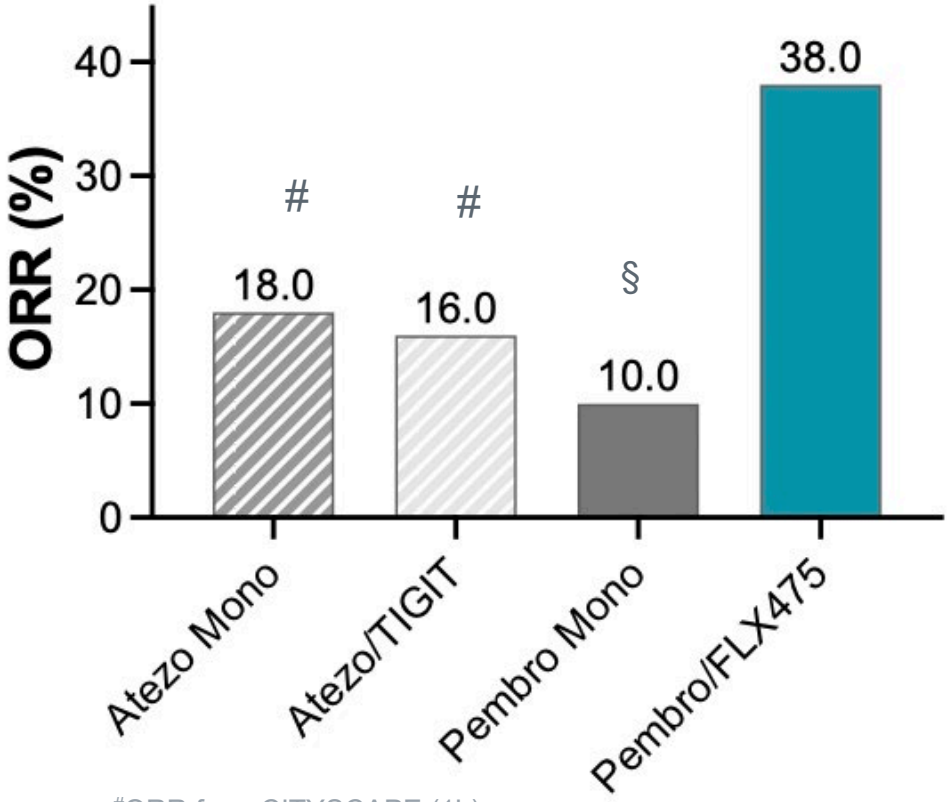
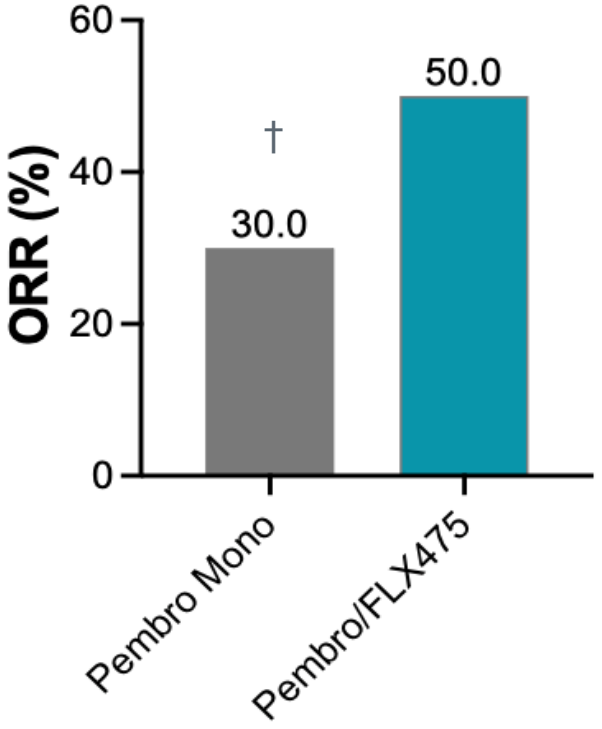
Differentiated FLX475/Pembrolizumab Efficacy Across PD-L1 Subgroups

PD-L1 Low (TPS 1-49%) NSCLC



#ORR from CITYSCAPE (1L);
§ORR from Keynote-010 (previously treated)

PD-L1 High (TPS ≥50%) NSCLC



†ORR from Keynote-010 (previously treated)

Cross trial comparisons;
Data do not represent randomized comparisons

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Safety: FLX475 Appears Well-Tolerated and Combinable

- >300 patients with advanced cancer dosed (including several up to 2-year maximum time on study)
- No immune-related AEs observed related to FLX475 monotherapy
  - Consistent with MOA; no depletion of T_{reg}, expected only to affect CCR4-mediated recruitment of T_{reg} into tumors
- No observed increased/new immune toxicity over pembrolizumab alone
- No FLX475-related laboratory changes or target-related toxicities
- Only FLX475-related AE observed has been asymptomatic and reversible low-grade QT prolongation in minority (<20%) of patients
  - Managed with dose reduction from 100 mg to 50 mg PO QD

Conclusions

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  - **6.3 mo** median PFS in PD-L1+ vs. **4 mo** with pembro mono
- Favorable safety profile with potential for broad combinability with other agents
- Data support continued development of FLX475/anti-PD-(L)1 combination therapy for CPI-naïve NSCLC

* Cutoff date Oct. 6, 2023; 11 patients remain on treatment; historical pembrolizumab monotherapy data from KEYNOTE-010 and KEYNOTE-001

Large Commercial Opportunities in 1L Advanced NSCLC

Line of Therapy	Combination	NSCLC Segment	US Market Size
1L	PD-(L)1/FLX475	PD-L1 high (TPS ≥ 50%)	27,300
	PD-(L)1/FLX475/Chemo	All PD-L1 (TPS = 0-100%)	106,000
	PD-(L)1/FLX475/TIGIT	PD-L1 high (TPS ≥ 50%)	27,300

Key Takeaways and Upcoming Milestones

- **Zelnecirnon**: first-in-class safe oral designed to be preferred option across a range of inflammatory diseases; in Phase 2b study in AD and Phase 2a study in asthma
- **Tivumecirnon**: first-in-class selective oral tumor T_{reg} inhibitor with monotherapy activity and encouraging anti-PD-1 combo efficacy in CPI-naïve NSCLC
- **Planned Key Milestone**
  - **mid 2024**: ZEL Phase 2b AD topline data