Creating Novel Therapeutics
For patients with Excellent Experts
In Drug Design

VORONOI

IR BOOK

November 24, 2026

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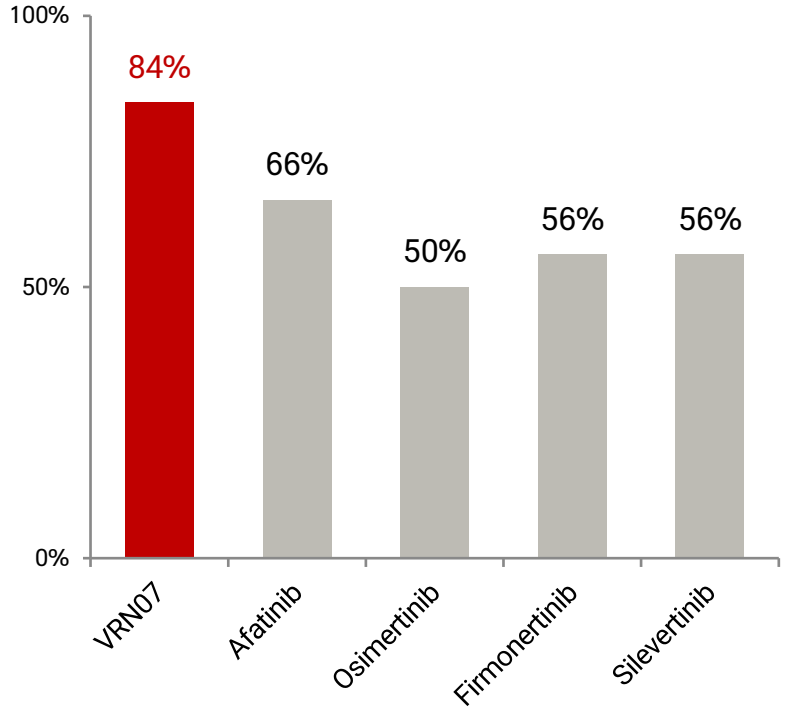
VRN07

EGFR NSCLC Targeted Therapy

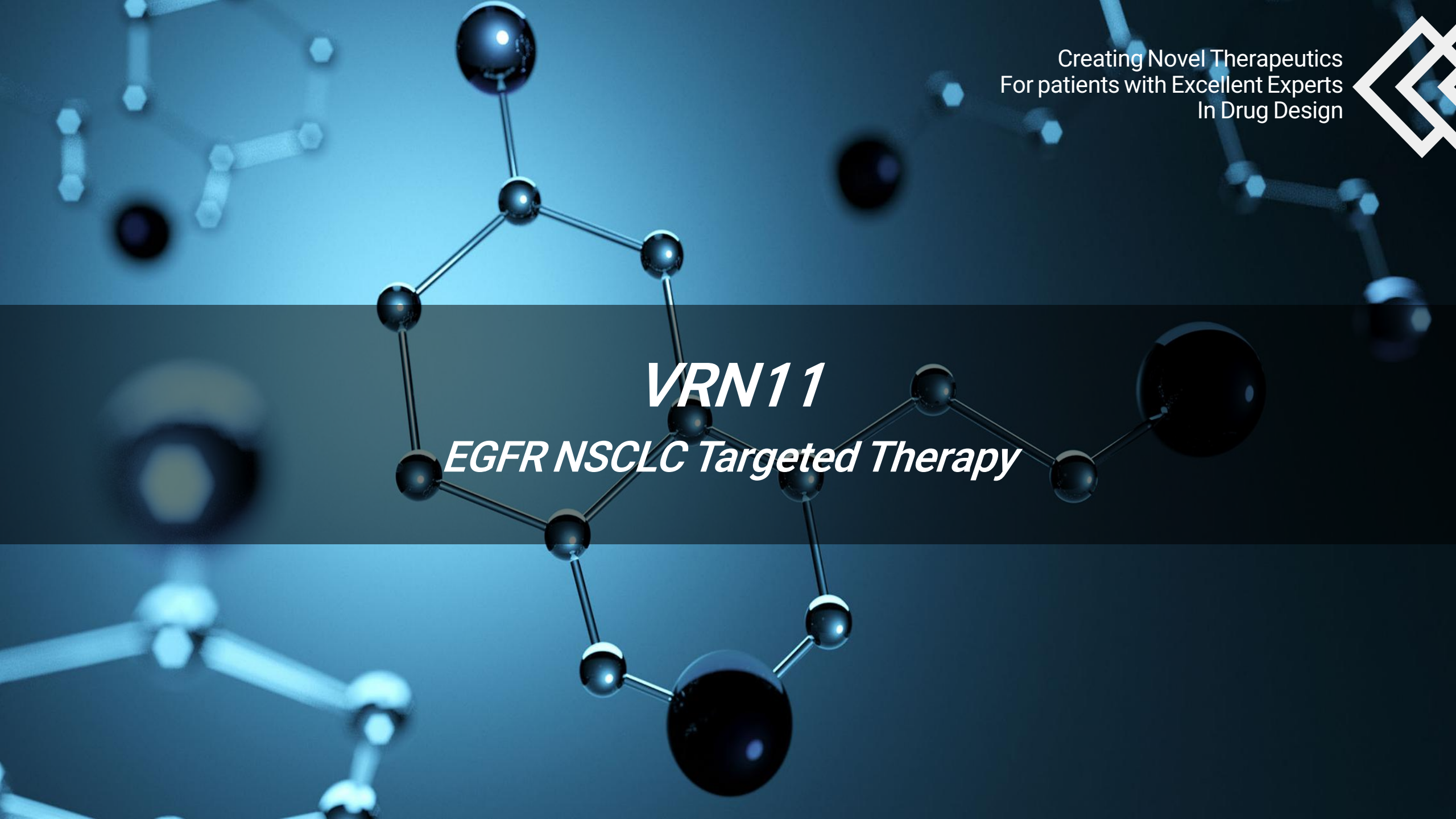
VRN07(Enozertinib)：EGFR Atypical mutation Competitive Landscape

	Enozertinib (Oric-114；VRN07)	Afatinib	Osimertinib	Firmonertinib		Silevertinib
Clinical study	Ph1b	Ph2	Ph2	Ph1b		Ph2
				160mg	240mg	
ORR	84%	66%	50%	43.5%	68.2%	56%
CNS Activity	CNS ORR 67% CNS CR 40%			CNS ORR 53%		
≥G3 TRAE	23%	44%	23~34%	20%	23%	60%
Discontinuations	0	8~9%	7~13%	4%	0	14%

PACC mutation ORR：VRN07 84%
higher efficacy compared to competitors



Source：Enozertinib：EMSO2026；Afatinib：LUX-Lung2/3/6, ACHILLES study；Osimertinib：KCSG-LU15-09 AURA3, FLAURA2 ADAURA study；Firmonertinib：Arrivent biopharma(June 23, 2025)；Silevertinib：Phase2 results Webcast(May 21, 2026)



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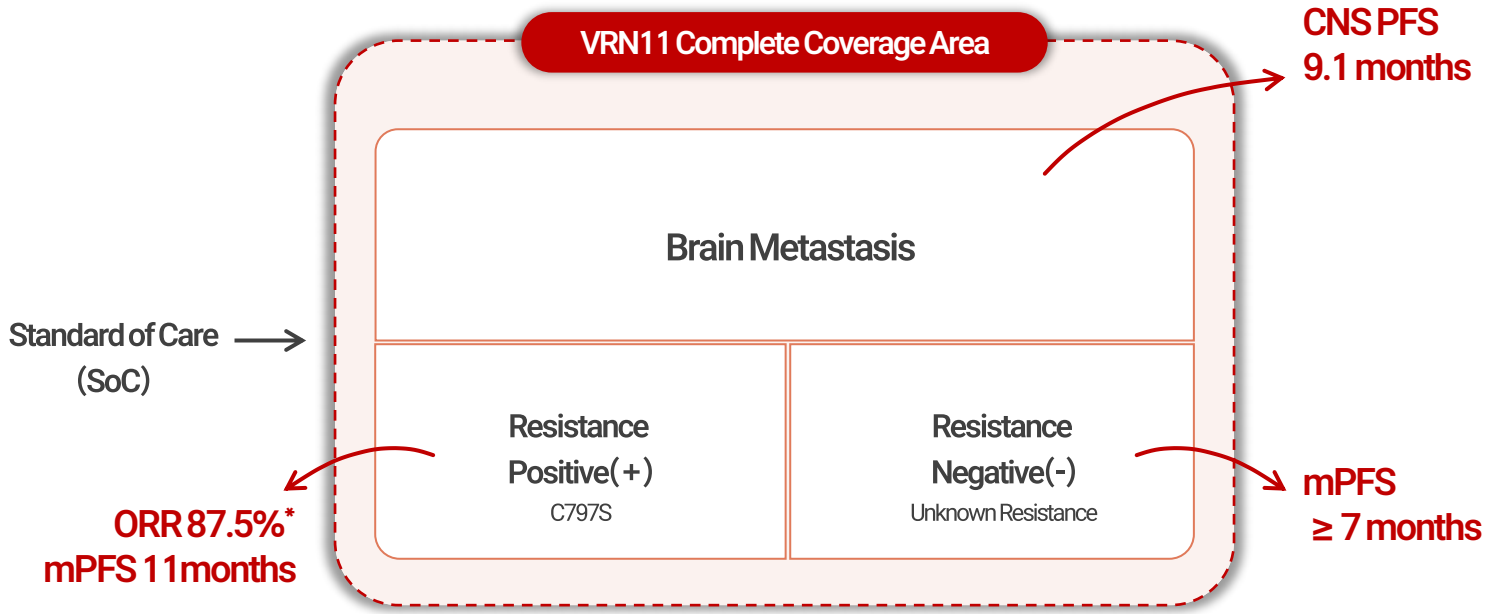
VRN11

EGFR NSCLC Targeted Therapy

1차 치료(1L) 임상 개시의 근거: 2차 치료에서 입증된 광범위한 효능

내성 변이 유무 및 뇌전이 유무를 가리지 않는 커버리지를 통해 표준치료와 경쟁 가능한 임상적 근거 축적 → 1차 표준치료(1L SoC) 패러다임 전환 기대

[EGFR-mutant NSCLC] 1L SoC 이후 **VRN11의 커버리지(Broad Coverage)**



1차 치료(1L) 임상 개시의 근거

- Osimertinib 포함 이전 치료 이후 환자를 대상으로 한 후속(2L+) 임상에서 우수한 치료 효과 확인
- Osimertinib 승인 용량 대비 높은 표적 억제력(Target engagement) 확인
- 우수한 안전성 프로파일 (≥Grade 3 약물관련 이상반응 2%)

1L 치료 임상 개시

- ✓ 호주, 홍콩, 싱가포르, 말레이시아, 태국 등에서 1b/2상 진행 중
- ✓ 다수의 글로벌 병원의 저명한 연구책임자들의 임상 참여

Data cutoff October 9,2026, *유효용량(≥160mg)을 투약한 EGFR C797S 변이 환자군에서 100%의 객관적 반응률(7/8)
ORR, Objective response rate; PFS, Progression-free survival



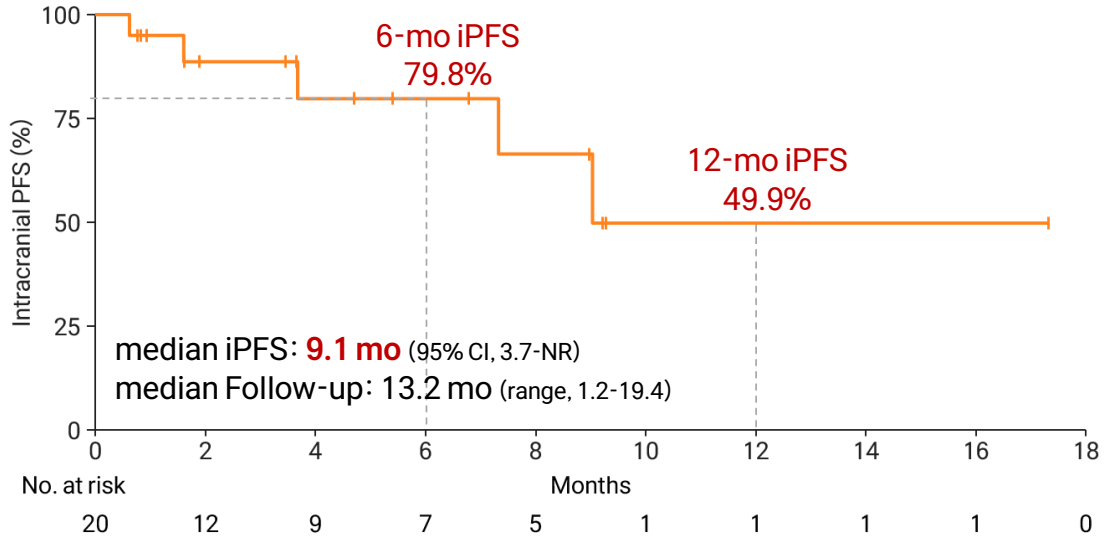
VRN11

Superior brain permeability, Better intracranial PFS

VRN11-Osimertinib 비교: 뇌전이 환자 생존 기간 개선(iPFS)

3세대 EGFR 치료제 이후 뇌 전이된 환자(C797S negative)를 대상으로 9.1개월의 두개내 무진행생존기간(iPFS) 및 두개내 완전관해(iCR) 20% 확인

[biomarker-negative pts] Comparison of iPFS (N=20)



With baseline BM	VRN11 (≥160 mg, C797S negative)	Osimertinib[1,2] (T790M negative)
6-mo iPFS	79.8%	31%
12-mo iPFS	49.9%	Not calculable
iPFS	9.1 months (3.7-NR)	3.5 months (1.0-NR)

Prior Lines, median (range)	3 (1-9)
Prior 3G EGFR TKI	17/20 (85.0%)

Intracranial best response by RANO-BM

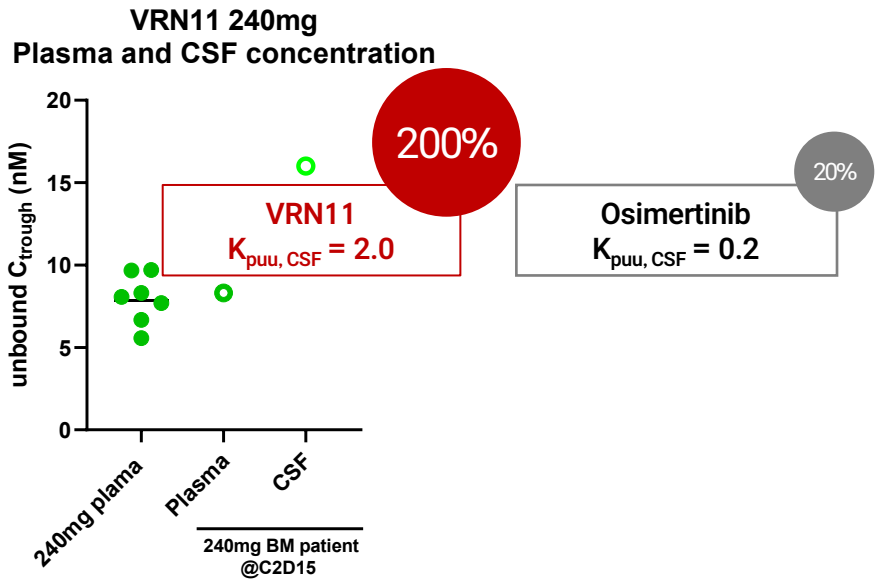
Base CNS lesion	VRN11	Osimertinib
Patients, n	20	11
CR, n	4 (20%)	0 (0%)
PR, n	0 (0%)	1 (9.1%)
SD, n	15 (75%)	5 (45.5%)
Non-CR/Non-PD, n		
PD, n	1 (5%)	2 (18.2%)
Disease control, n	19 (95%)	6 (54.5%)

Data cutoff: October 9,2026
BM, brain metastasis; CNS, central nervous system; CR, complete response; iPFS, intracranial progression-free survival; Non-CR/Non-PD, non-complete response/non-progressive disease; PFS, progression-free survival.
[1]Eide IJZ, et al. Osimertinib in T790M-positive and -negative patients with EGFR-mutated advanced non-small cell lung cancer: the TREM study. Lung Cancer. 2020;143:27–35.
[2]Eide IJZ, et al. Intracranial effect of osimertinib in relapsed EGFR-mutated T790M-positive and -negative non-small cell lung cancer patients: results from a phase II study. Acta Oncol. 2021;60(12):1565–1571.

VRN11-Osimertinib 비교: 뇌 투과율 및 Target Engagement

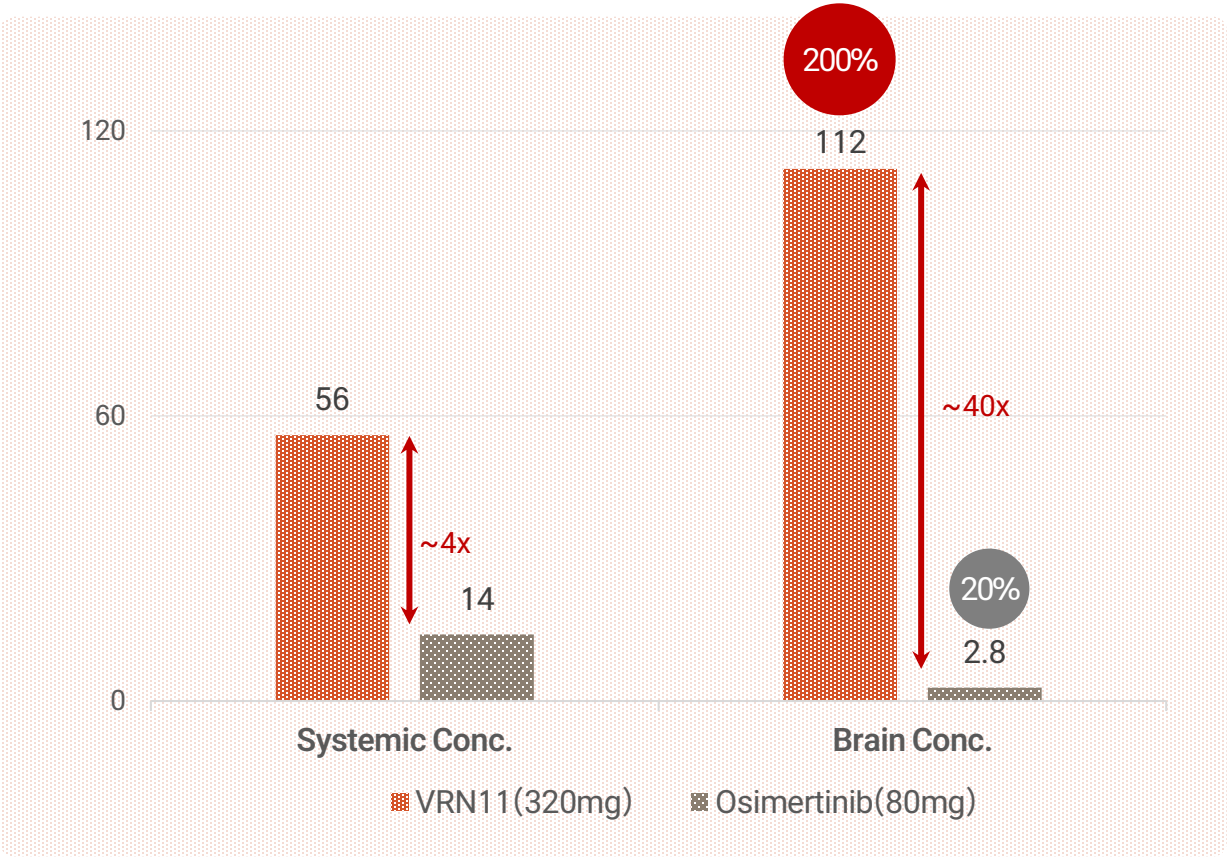
Osimertinib의 뇌 투과율은 20%인 반면, VRN11은 글로벌 최초로 **뇌 투과율 200%**에 대한 **Human PoC Data** 확보
Osimertinib 대비 **폐에서 4배, 뇌에서 40배** 우수한 종양 처치력(Target Engagement) 확인

환자에서의 뇌 투과율(Free Drug Concentration in Brain, $K_{puu,CSF}$)



	Monkey	Human
$K_{p,uu,csf}$	2.7	2.0*
$K_{p,uu,csf}$ of Osimertinib in human has been reported, 0.22[1]		

Target engagement 비교(Systemic - Brain)

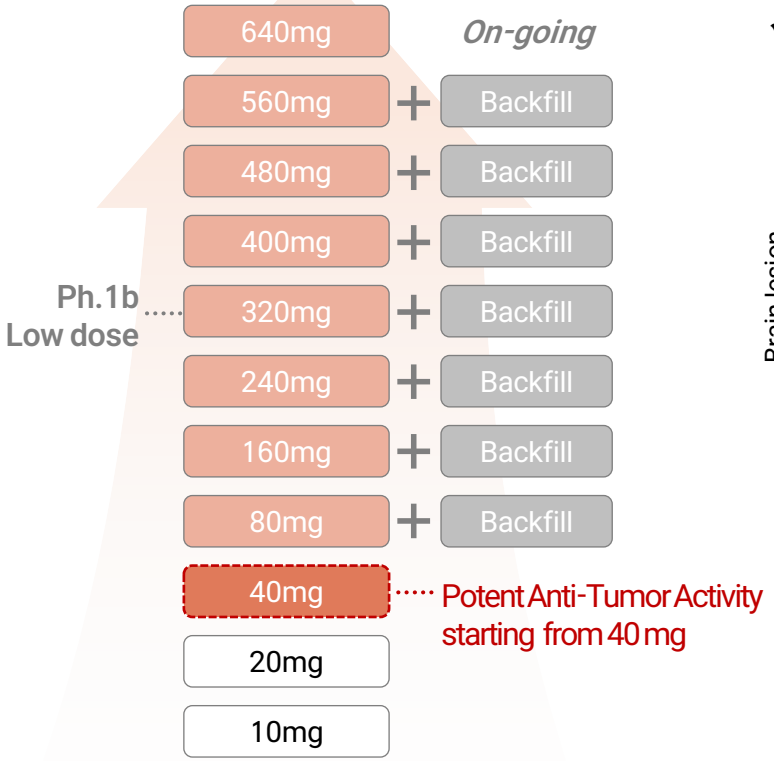


Source: [1]Park S, et al. J Clin Oncol. 2024;42(23):2747–2756
*A representative human PPB, 98.3% was used for calculation, $K_{puu, CSF}$ measured in 1 patient who received 240 mg

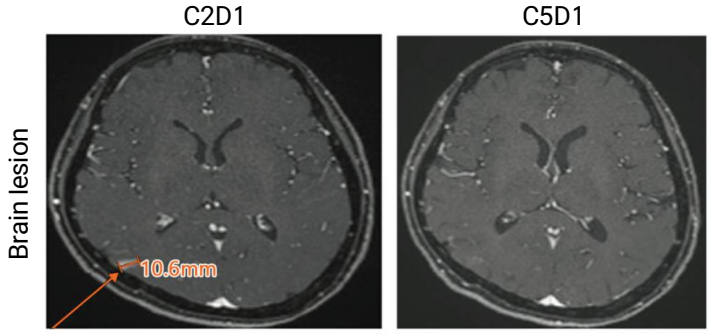
Case Report: 뇌전이 환자에서의 치료 효과 (1)

임상 1상 중 40mg부터 뇌 전이 환자에 대한 항암 효과 확인
용량 의존적 혈중 Free drug 농도 증가 확인

Phase 1a. Dose escalation

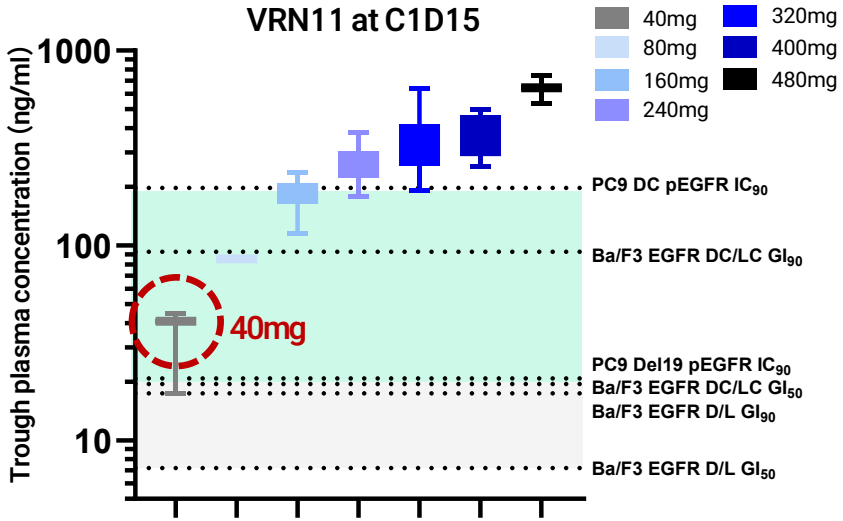


✓ 40mg부터 확인된 유의미한 항종양 효과



- Lung, brain, and pleural metastasis
- Two prior systemic treatments, including Dacomitinib and Osimertinib
- Tumor disappearance of CNS lesion

✓ 용량 의존적 혈중 Free drug 농도 증가

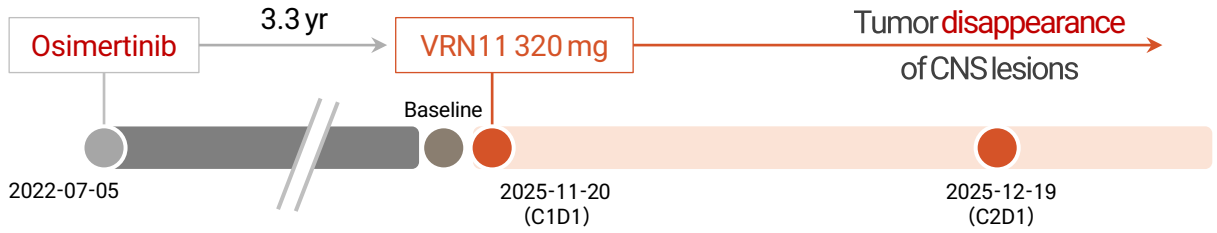


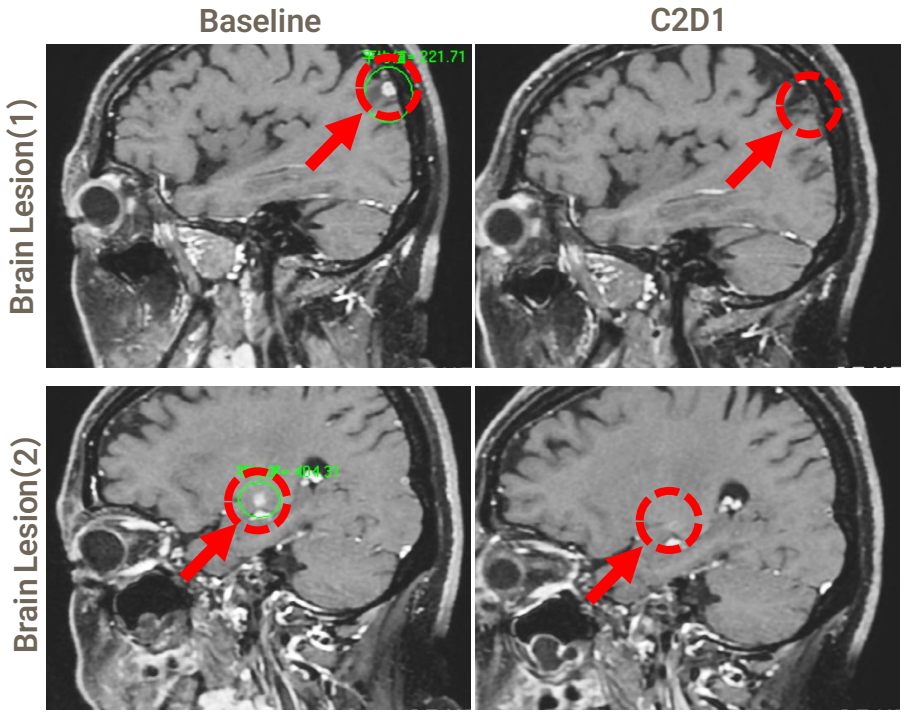
PR, Partial response; SD, Stable disease; PD, Progressive disease; TRAE, treatment-related adverse event; SAE, serious adverse event; DLT, dose limiting toxicity

Case Report: 뇌전이 환자에서의 치료 효과 (2)

3세대 EGFR TKI 치료 후 뇌전이 환자에서 VRN11 투여 후 첫 종양평가 시 뇌 병변 소실 확인
폐 병변 50% 감소로 Overall PR(partial response) 달성

320mg: 47-yr female with EGFR Del19/C797S NSCLC





Baseline and Treatment History

- Lung, Brain, Bone metastasis
- Disease progression **after Osimertinib**

VRN11 Treatment

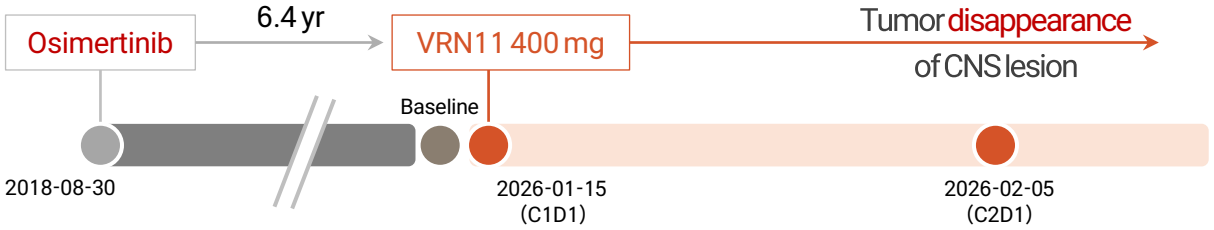
- Lung target lesion: 50% tumor reduction
- **Two brain lesions*** were **absent** at first TA
- Baseline ctDNA of EGFR mutation cleared
- Overall best response: PR

PR, Partial response; SD, Stable disease; PD, Progressive disease; TRAE, treatment-related adverse event; SAE, serious adverse event; DLT, dose limiting toxicity
*Non-target lesion

Case Report: 뇌전이 환자에서의 치료 효과 (3)

3세대 EGFR TKI 치료 후 뇌전이가 발생한 환자에서 VRN11 투여 후 첫 종양평가 시 뇌 병변 소실 확인
폐 병변 38% 감소로 Overall PR(partial response) 달성

400mg: 71-yr female with EGFR L858R NSCLC

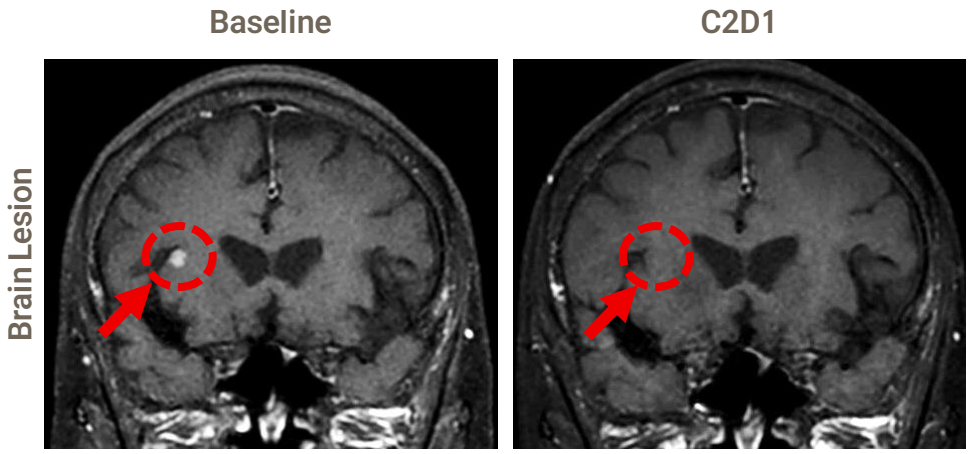


Baseline and Treatment History

- Lung and brain metastasis
- Prior EGFR TKI: **Osimertinib, Lazertinib**

VRN11 Treatment

- Lung target lesion: 38% tumor reduction
- **Brain lesion*: CR**
- Overall best response: PR



PR, Partial response; SD, Stable disease; PD, Progressive disease; TRAE, treatment-related adverse event; SAE, serious adverse event; DLT, dose limiting toxicity
*Non-target lesion



VRN11

EGFR 2nd Line treatment

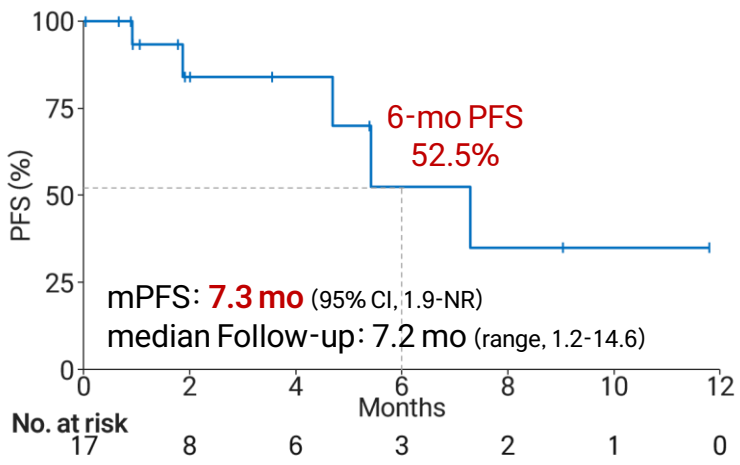
VRN11-Osimertinib 비교: Progression-free survival(PFS); 2L treatment

화학요법 치료 이력 환자 대상 VRN11 mPFS 7개월 이상
Heavily pretreated된 환자임에도 불구하고 Osimertinib 2.8 ~ 4.07개월 대비 현저한 생존기간 연장 효과 입증

C797S -negative

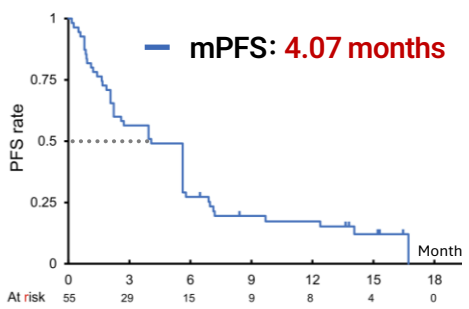
VRN11: Progression-Free Survival (PFS),

Prior Treatment	
1/2G EGFR TKI	64.7%
3G EGFR TKI	82.4%
Chemotherapy	76.5%

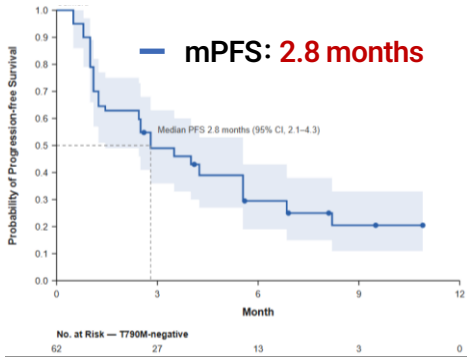


T790M -negative

Osimertinib: Progression-Free Survival (PFS)[1,2]



WJOG12819L(80 mg), after 1st/2nd-gen. EGFR TKI and platinum



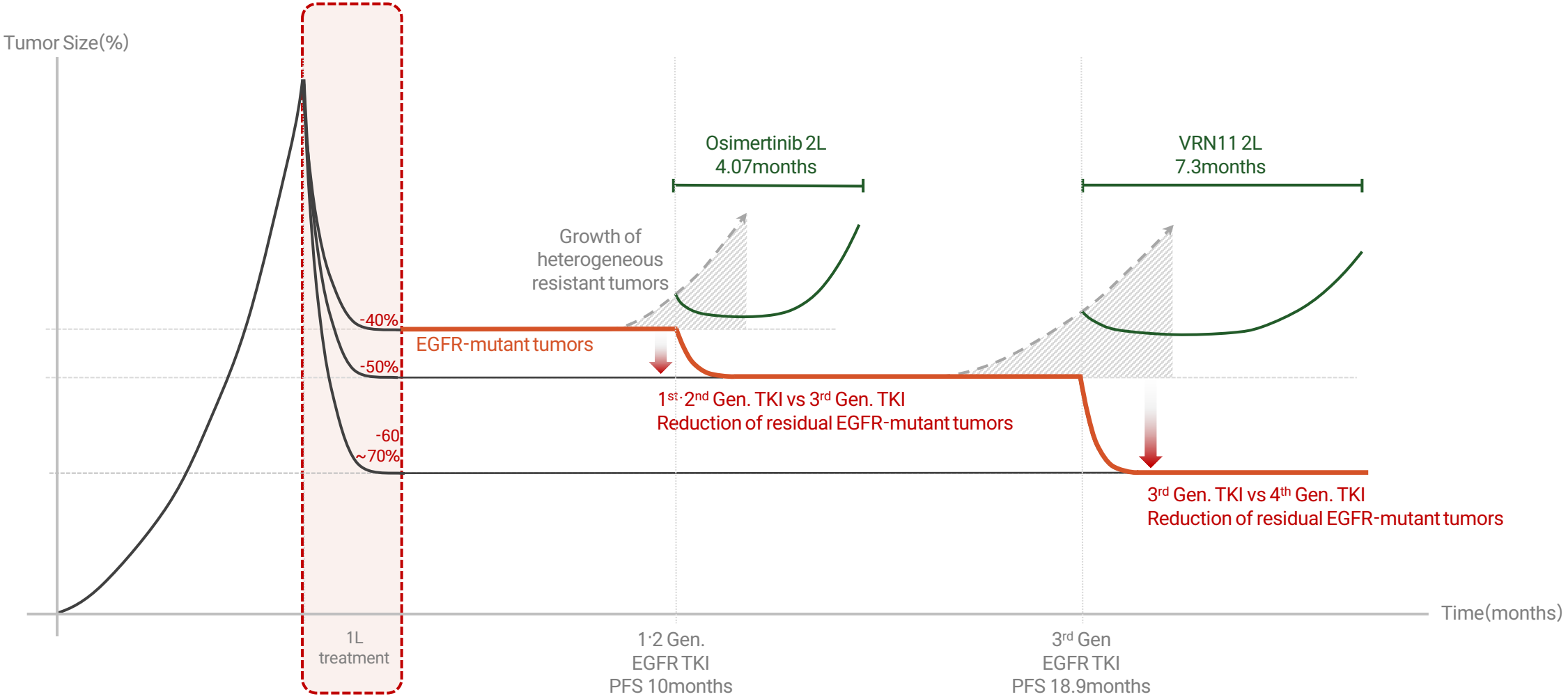
AURA Ph.1 (20–240 mg), after 1st/2nd-gen. EGFR TKI

	VRN11 (C797S negative, ≥ 320 mg)	Osimertinib[1] (T790M negative)	Osimertinib[2] (T790M negative)
mPFS	7.3 months (95% CI, 1.9-NR months)	4.07 months (95% CI 2.1-4.3 months)	2.8 months (95% CI 2.1-4.3 months)

Data cutoff: October 9,2026
PFS, Progression-Free survival;
Source: [1]Takeda M, et al. Lung Cancer. 2023;177:44–50. [2]Jänne PA, et al. N Engl J Med. 2015 Apr 30;372(18):1689-99.

약물의 세대별 종양 억제력과 종양 증식력의 균형

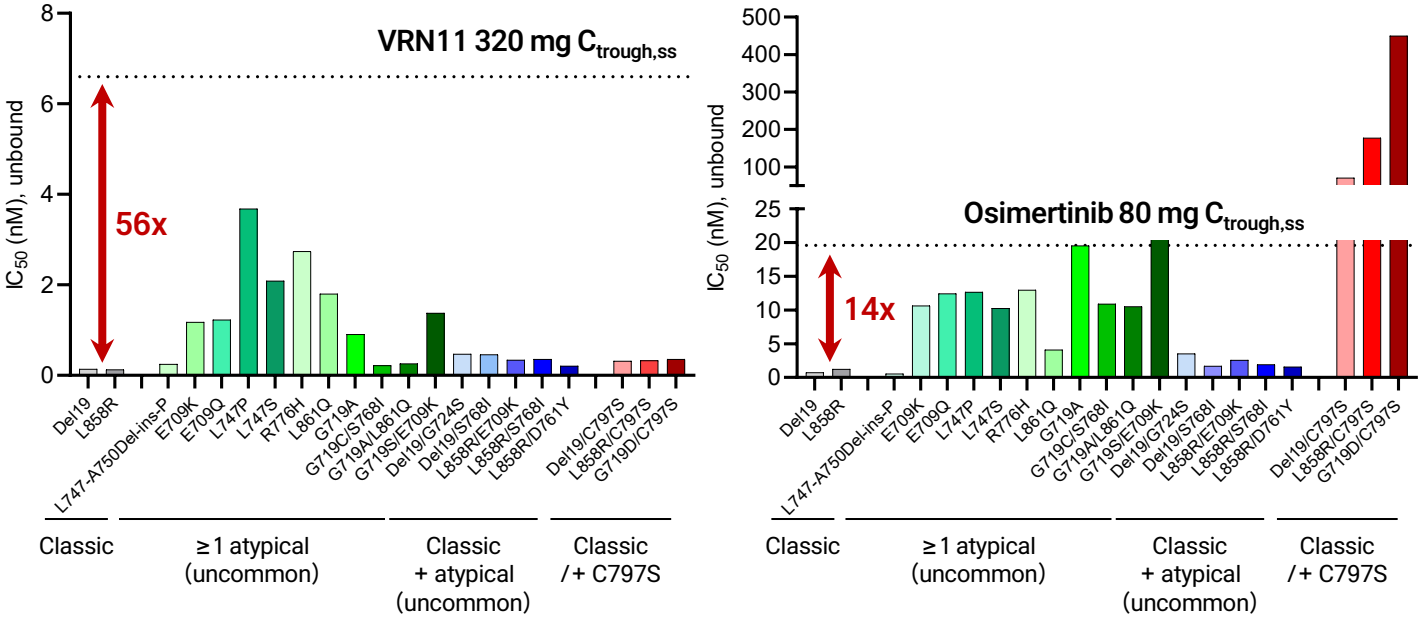
VRN11의 우수한 표적 억제력이 EGFR 의존적인 종양을 3세대 EGFR-TKI보다 더 효과적으로 감소시킴으로써 PFS 연장



EGFR 변이 비소세포폐암에 대한 전임상 및 임상적 효능 근거

VRN11 320mg에서 전반적인 EGFR 변이에 대한 우수한 활성 확인
EGFR del19 및 L858R에서 Osimertinib 80mg 대비 4배 강력한 Target Engagement 확보, 탁월한 뇌 투과율로 CNS 영역서 차별적 우위 확인

In vitro Target Engagement in Ba/F3-engineered Cell Lines



Target engagement ratio(TER)

Systemic TER

	VRN11 320mg	Osimertinib 80mg	VRN11 / Osimertinib
Classic	56	14	~4x
Classic + C797S	22	< 1	140x
Classic + Atypical	20	9	2x
Atypical	5	2	3x

x 2.0

x 0.2

Brain TER

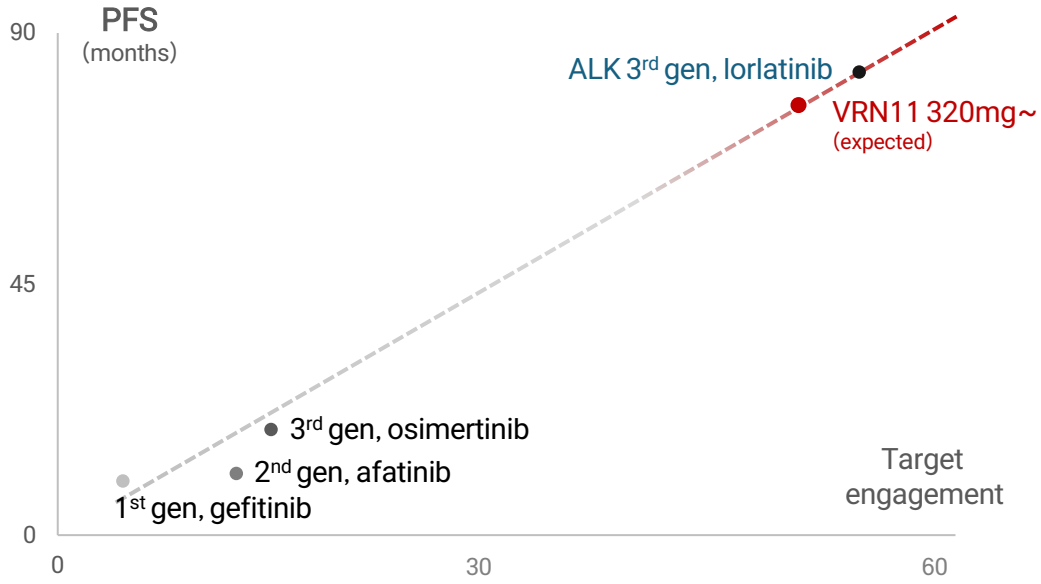
	VRN11 320mg	Osimertinib 80mg	VRN11 / Osimertinib
Classic	112	2.8	~40x

Source: ASCO2026

PFS-CNS CR-Target engagement

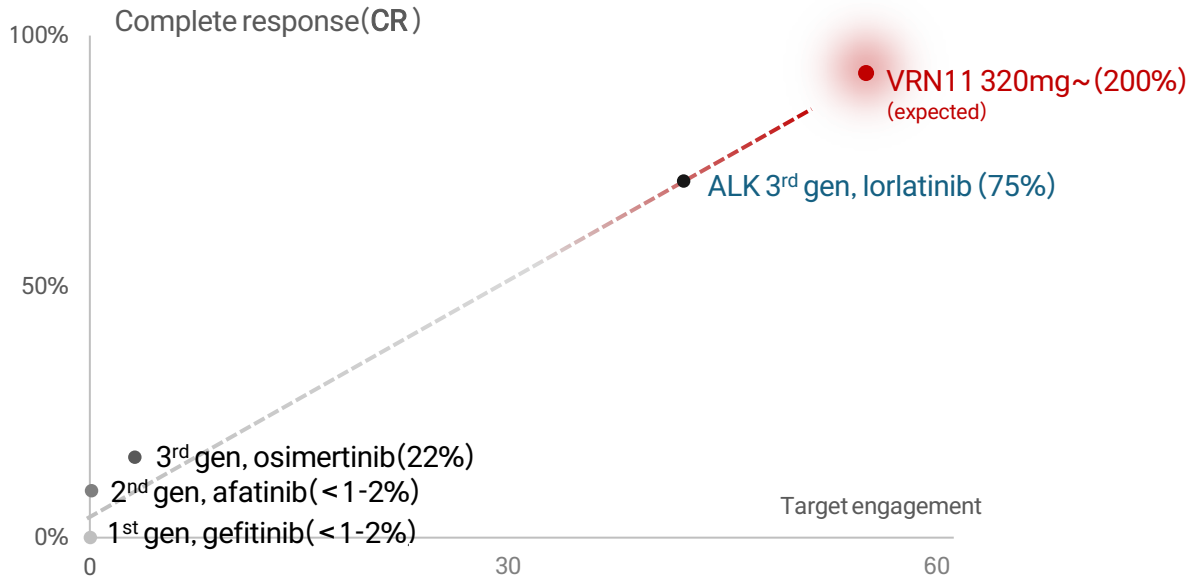
1차 치료 임상에서 기대되는 주요 성과: 두개내 완전관해(iCR)율 70% 이상 및 무진행생존기간(PFS) 7년 이상

Systemic



mPFS	EGFR		ALK
	Osimertinib	VRN11	Lorlatinib
2L+	4.07 m	7.3 m	7.3 m
1L	18.9 m	> 7 y (expected)	> 7 y

CNS

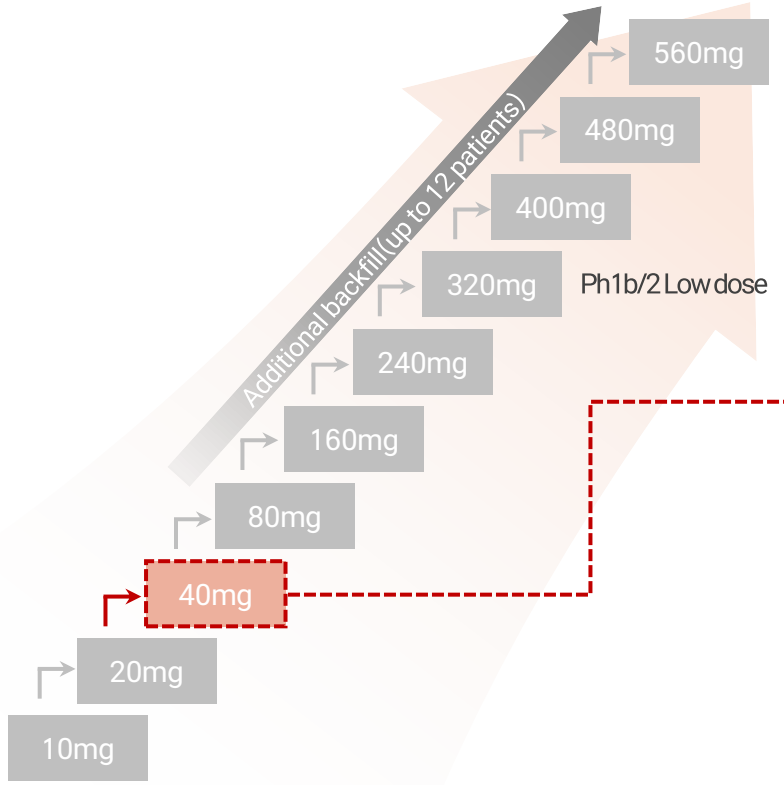


CNS CR	EGFR		ALK
	Osimertinib	VRN11	Lorlatinib
2L+	0%	20%	20%
1L	16%	> 70% (expected)	71%

Source: Douillard JY, et al. Br J Cancer 2014;110:55-62, Sequist LV, et al. J Clin Oncol. 2013 Sep 20;31(27):3327-34, Soria JC, et al. N Engl J Med. 2018 Jan 11;378(2):113-125, Shaw AT, et al. Ann Oncol. 2026 Sep;37(9):1242-1252, Zhao J, et al. Clin Lung Cancer. 2013 Mar;14(2):188-93, Kim M, et al. Drug Metab Dispos. 2019 Apr;47(4):393-404, Park S, et al. J Clin Oncol.2024;42(23):2747–2756, Sun S, et al. J Clin Pharmacol. 2022;62(9):1170-1176, Lu S, et al. Cancer Commun (Lond). 2024 Sep;44(9):1005-1017, Kang L, et al. Front Oncol. 2023 Feb 23;13:1094195, Shaw AT, et al. N Engl J Med. 2020 Nov 19;383(21):2018-2029, Jänne PA, et al. J Clin Oncol. 2024 Mar 1;42(7):808-820, Eide IJZ, et al. Acta Oncol. 2021;60(12):1565–1571, Solomon BJ, et al. Lancet Oncol. 2018;19(12):1654-1667, Takeda M, et al. Lung Cancer. 2023 Mar;177:44-50, in-house

Case Report: 임상 1상 중 40mg부터 뇌 전이 환자에 대한 항암 효과 확인

Phase 1a. Dose escalation

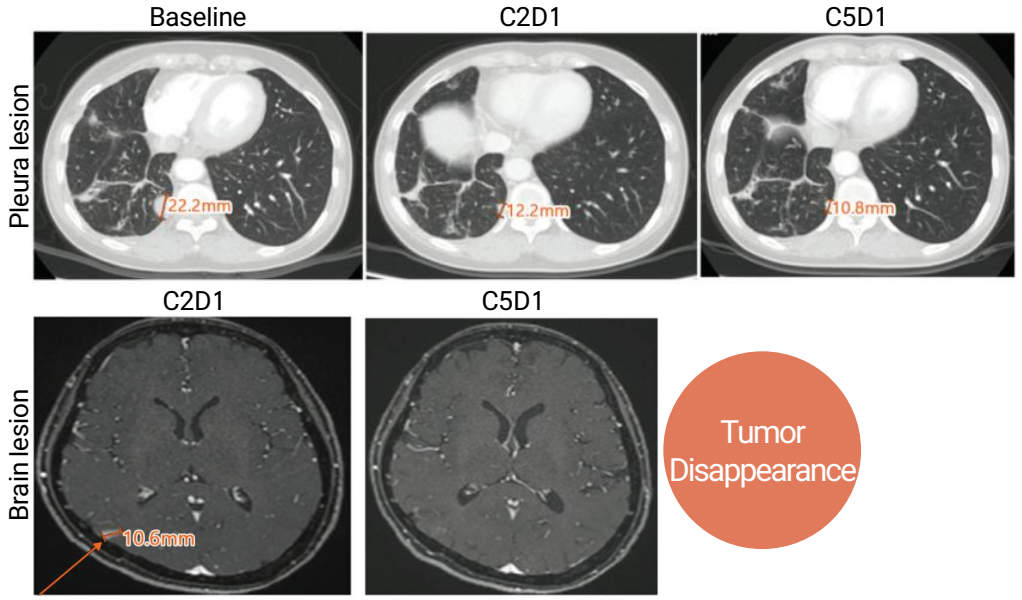


- Up to 12 backfill patients may be enrolled from the 80 mg cohort, subject to SMC safety confirmation.

40mg Case report

40mg

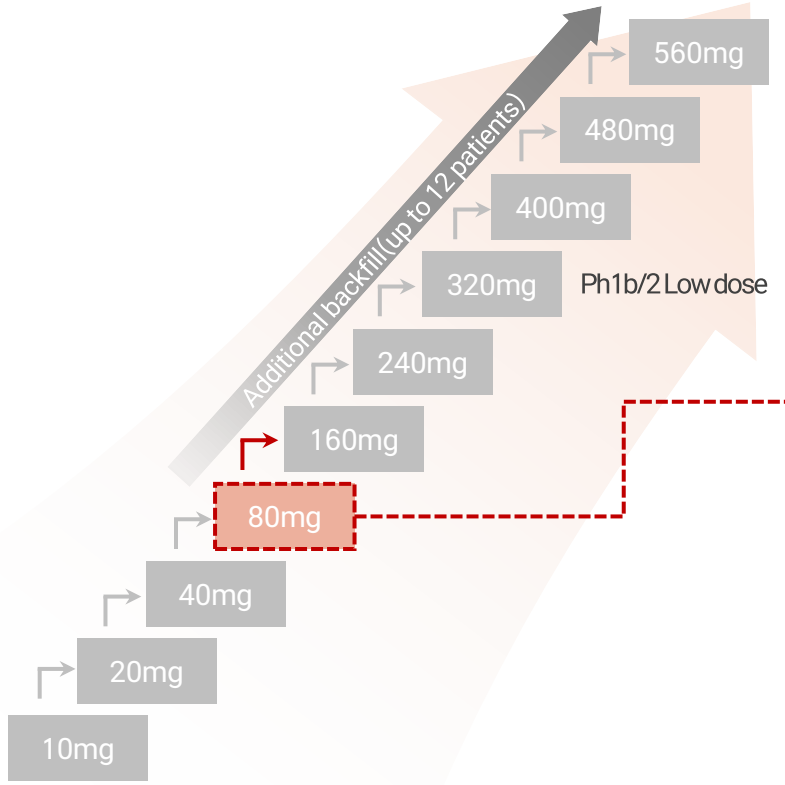
- Lung, brain, and pleural metastasis
- Two prior systemic treatments, including Dacomitinib and **Osimertinib**



PR, Partial response; SD, Stable disease; PD, Progressive disease; TRAE, treatment-related adverse event; SAE, serious adverse event; DLT, dose limiting toxicity

Case Report: 용량 증량에 따른 치료 효과 개선 (EGFR del19, 80 → 160mg)

Phase 1a. Dose escalation

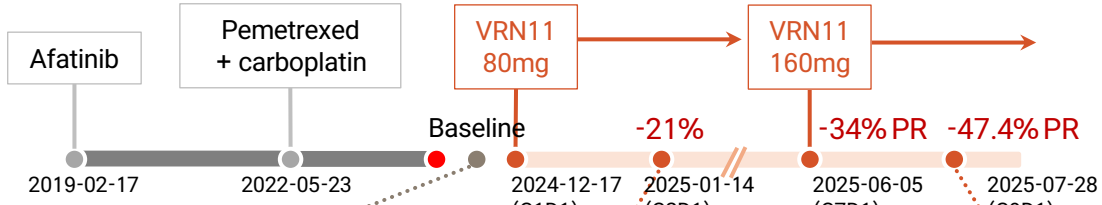


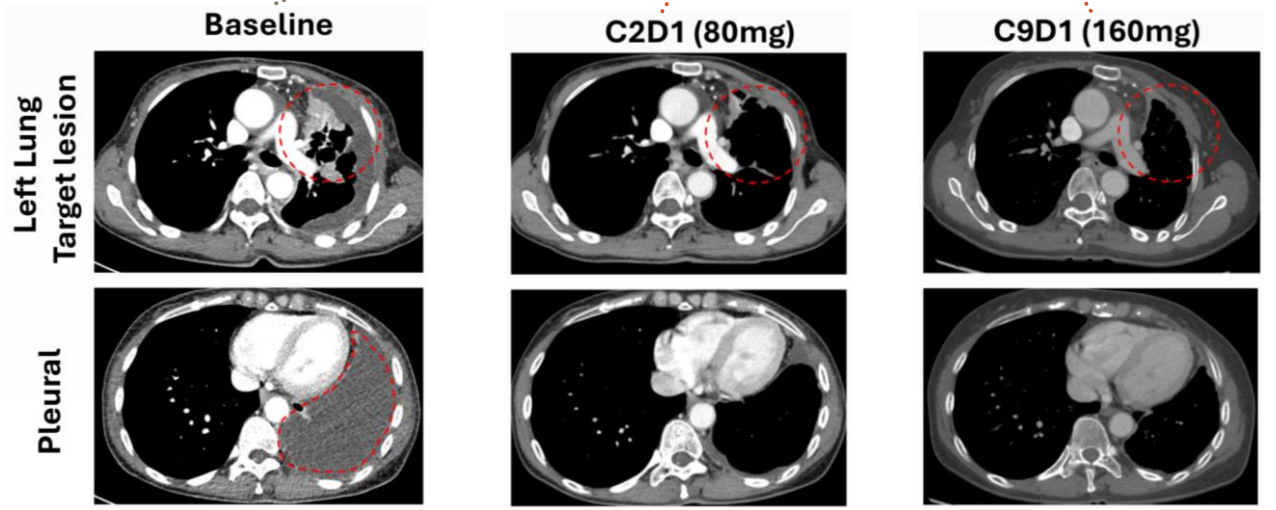
- Up to 12 backfill patients may be enrolled from the 80 mg cohort, subject to SMC safety confirmation.

80mg Case report

80mg → 160mg

- ≥ 19 months, Best response: PR
- Safety: **No TRAE**



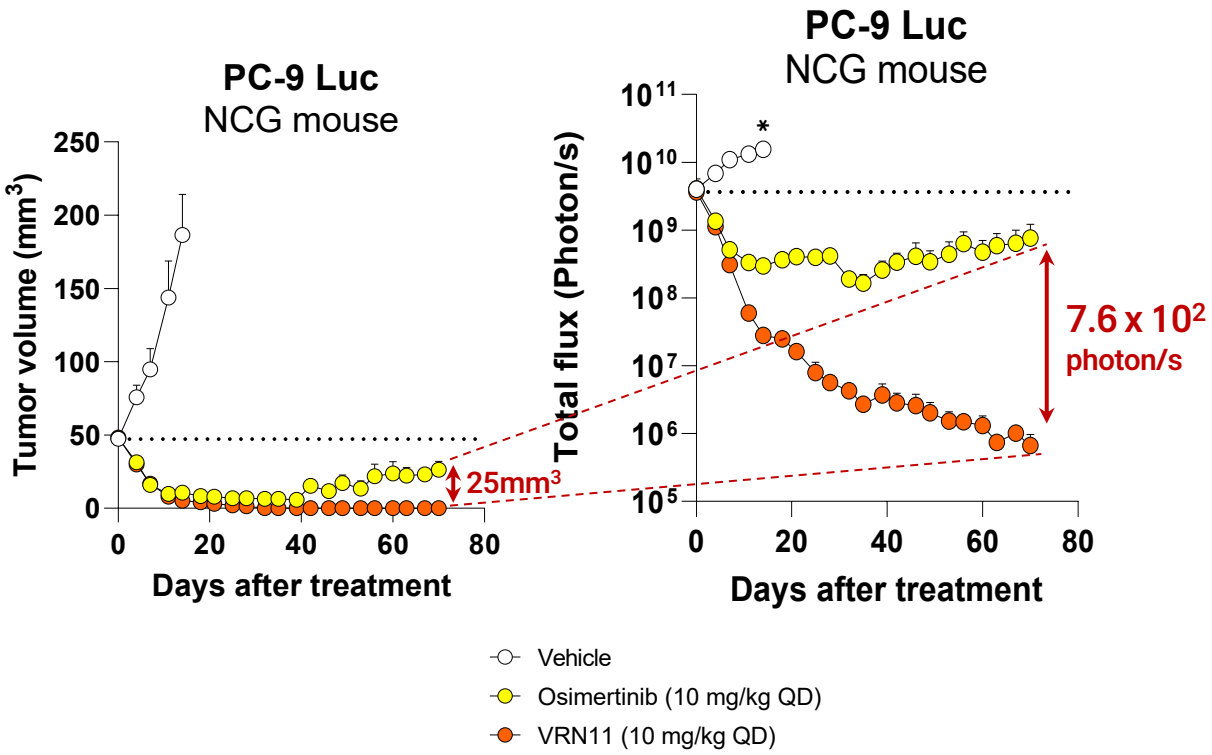


PR, Partial response; SD, Stable disease; PD, Progressive disease; TRAE, treatment-related adverse event; SAE, serious adverse event; DLT, dose limiting toxicity
Data cut-off July 2, 2026

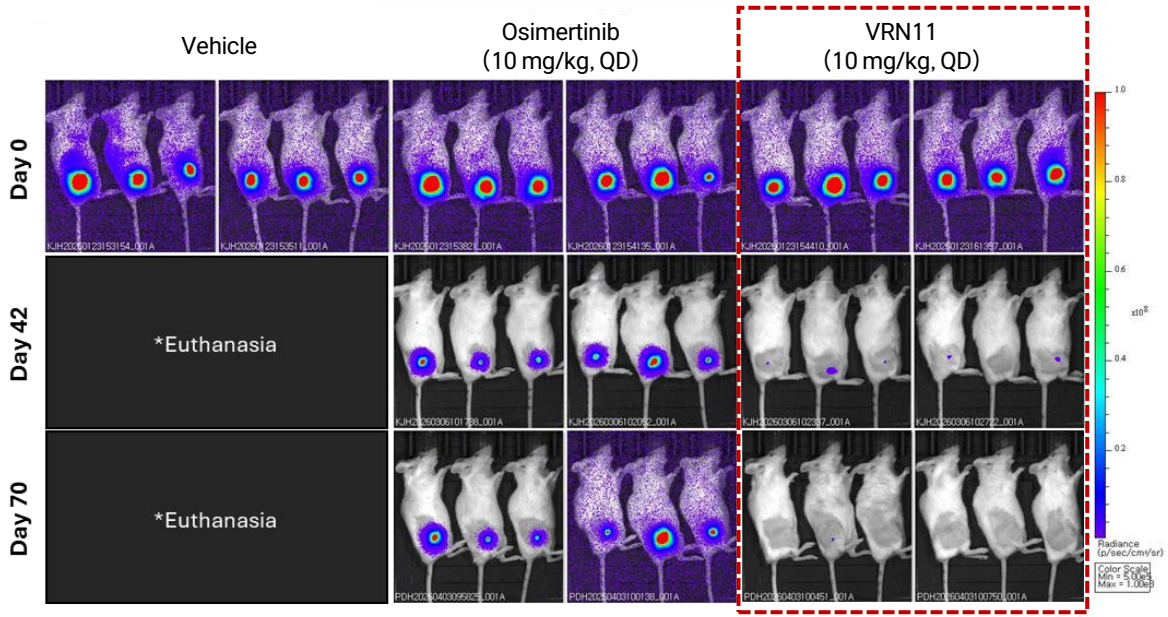
In vivo 모델을 통해 입증된 VRN11의 종양 반응 예측: Deeper Response

CDX 모델에서 Osimertinib 대비 깊은 종양 억제(Depth of Response) 효과 확인

Subcutaneous CDX model(PC9 _ Del19)

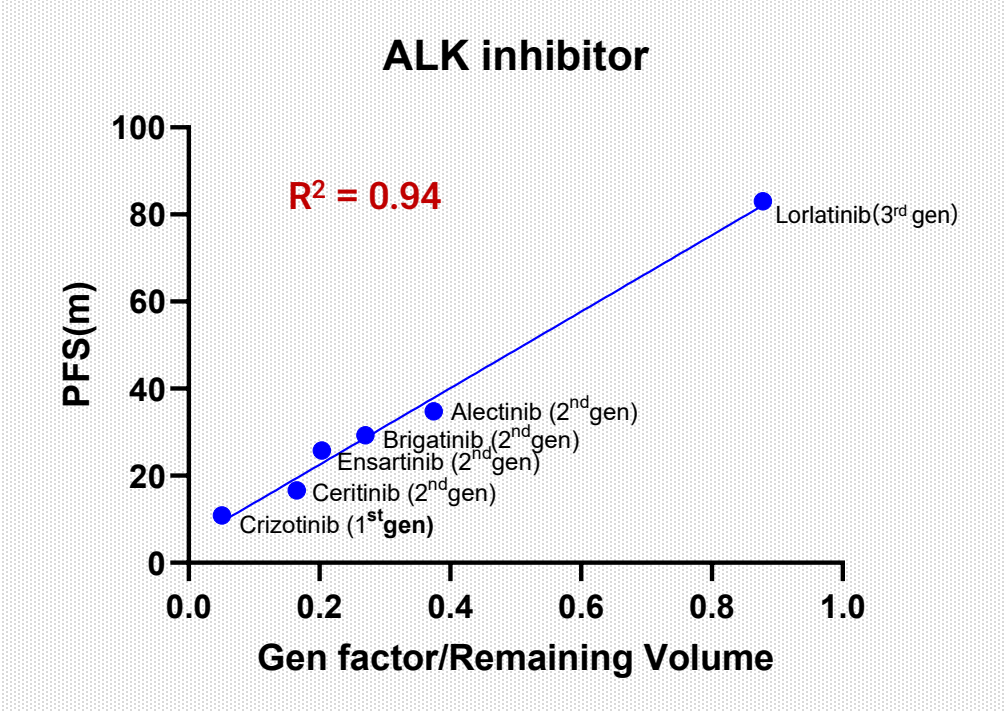


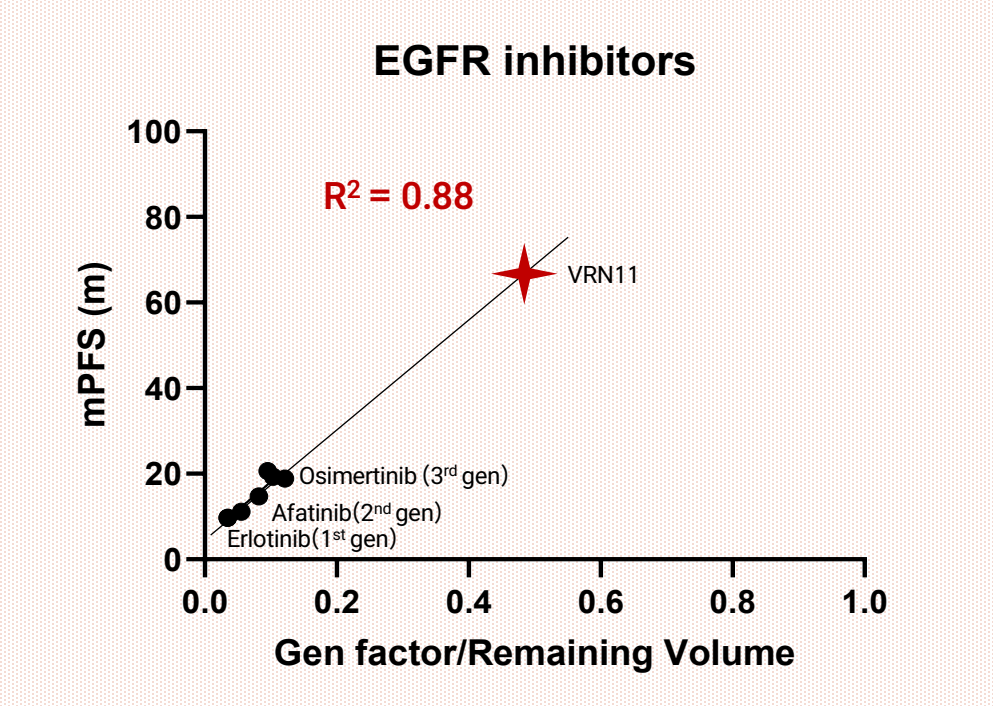
Luciferase signal in SC model

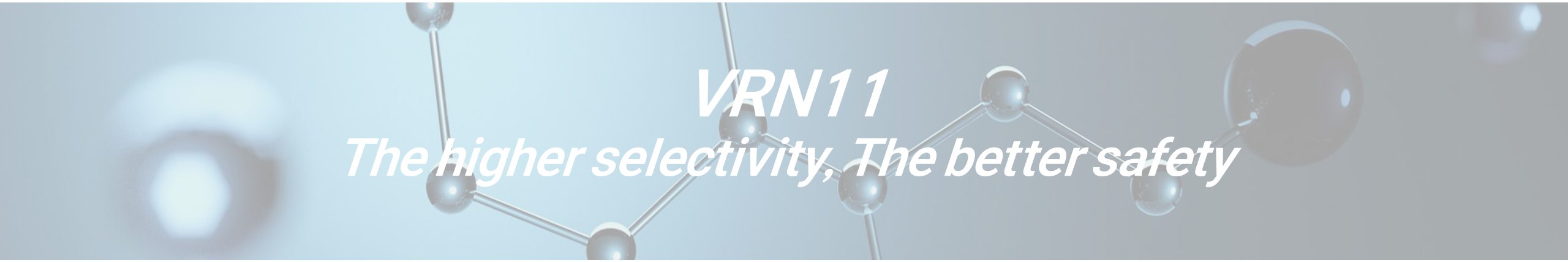


PFS 와 Depth of Response 간의 상관관계(ALK, EGFR)

ALK 사례에서도 Target Engagement가 높을 수록 종양 감소 폭이 크고, 결과적으로 PFS가 길어지는 현상 확인







VRN11

The higher selectivity, The better safety

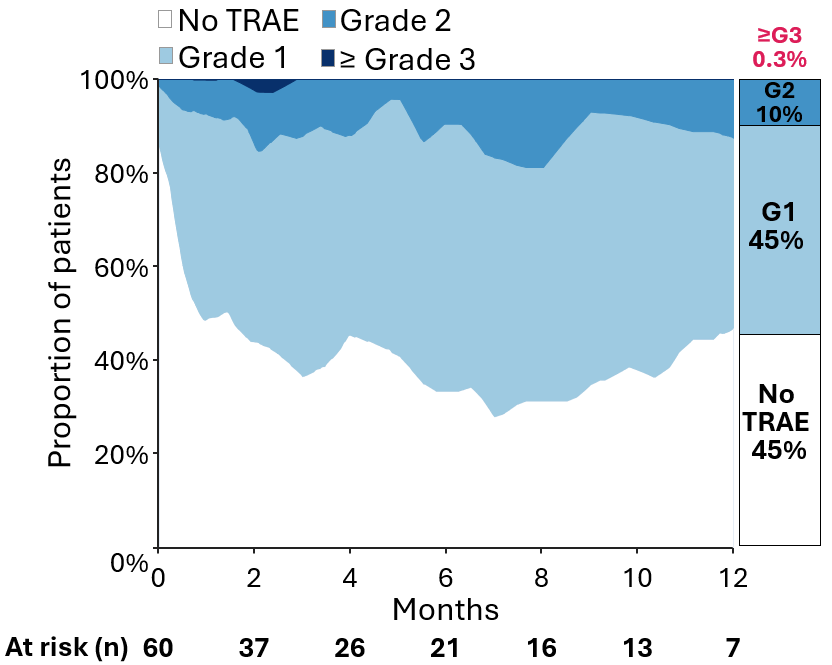
Safety Profile

Grade 3 이상의 약물 관련 부작용 2%(2/82)로 뛰어난 내약성 확인
약물 관련 부작용으로 인한 영구 투여 중단(Permanent discontinuation) 사례 없음

임상 1상 중 양호한 안전성 및 내약성 확인

Treatment-related adverse events**	Patients (10-560 mg, N=82)			
	G1	G2	≥ G3	Total
Any	28 (34)	20 (24)	2 (2)	50 (61)
EGFR-related				
Diarrhea	11 (13)	3 (4)	0 (0)	14 (17)
Pruritus	9 (11)	4 (5)	0 (0)	13 (16)
Rash maculo-papular	9 (11)	2 (2)	0 (0)	11 (13)
Rash	5 (6)	4 (5)	0 (0)	9 (11)
Dermatitis acneiform	5 (6)	0 (0)	0 (0)	5 (6)
Dry skin	4 (5)	1 (1)	0 (0)	5 (6)
Paronychia	3 (4)	2 (2)	0 (0)	5 (6)
Stomatitis	5 (6)	0 (0)	0 (0)	5 (6)
Non-EGFR-related				
Nausea	9 (11)	1 (1)	0 (0)	10 (12)
AST increased	7 (9)	1 (1)	0 (0)	8 (10)
ALT increased	7 (9)	0 (0)	0 (0)	7 (9)
Special interests				
Lung-related	0 (0)	0 (0)	1 (1)	1 (1)
QT prolongation	3 (4)	0 (0)	0 (0)	3 (4)

우수한 장기 안전성 입증: 160mg 이상 용량군 환자의 투약 기간별 부작용 추이(N=60)



✓ 전체 투약 기간의 90%가 경증 이하(부작용 없음 45%, G1 45%)로 관리되고, 중증 부작용(G3 이상)은 0.3%에 불과하여 우수한 장기 내약성 입증

Data cut-off October 9, 2026
**TRAEs occurring in ≥5% of patients and adverse events of special interest are shown.
[a] Proportion of patients on treatment at each point, by highest ongoing TRAE grade.
Right bar: pooled across all patients, % of on-treatment days by highest TRAE grade.

경쟁 약물의 안전성 프로파일 및 실제 임상 투여 현황(Osimertinib)

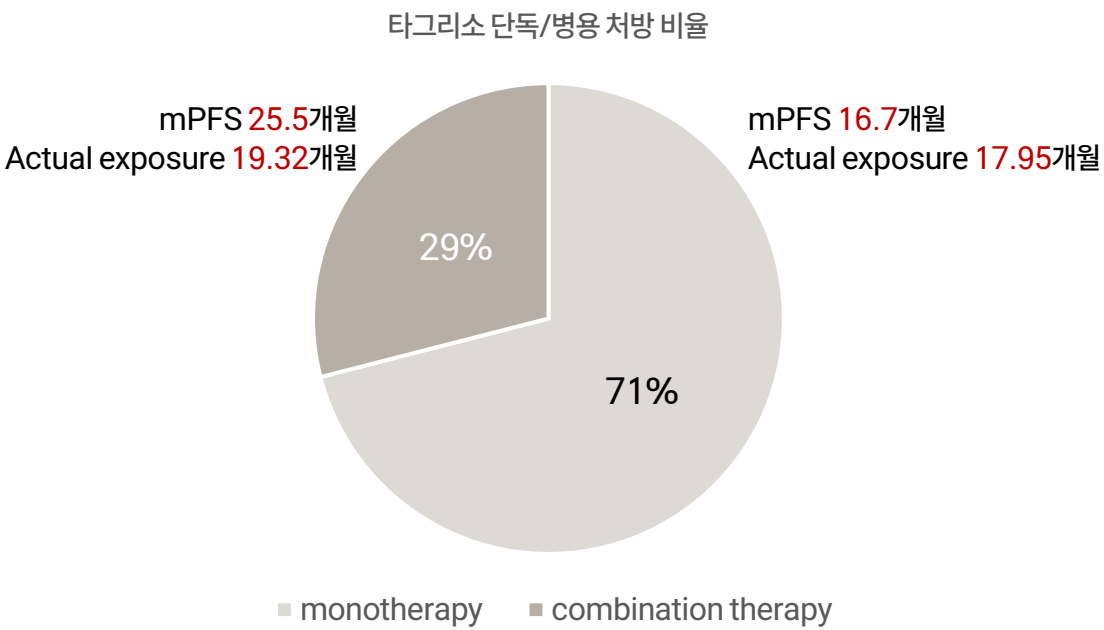
Osimertinib 병용요법의 경우, 높은 부작용으로 인해 실제 투여 기간이 무진행생존기간 대비 감소하고 처방률이 저하됨

Adjuvant		
ADAURA	대조군	Osimertinib
	재발율	DFS
2년	45%	
3년		84%
4년	62%	
5년		53%

Osimertinib 주요 임상별 안전성 프로파일 비교[1,2,3]

	ADAURA	AURA3	FLAURA2	
	단독	단독	단독	병용
Grade ≥3 AE any cause	23%	23%	34%	70%
Serious AE	20%	18%	19%	38%
Discontinuation due to AE	13%	7%	7%	12%
Dose interruption	27%	~19%	19%	44%
Dose reduction	12%	3%	3%	10%

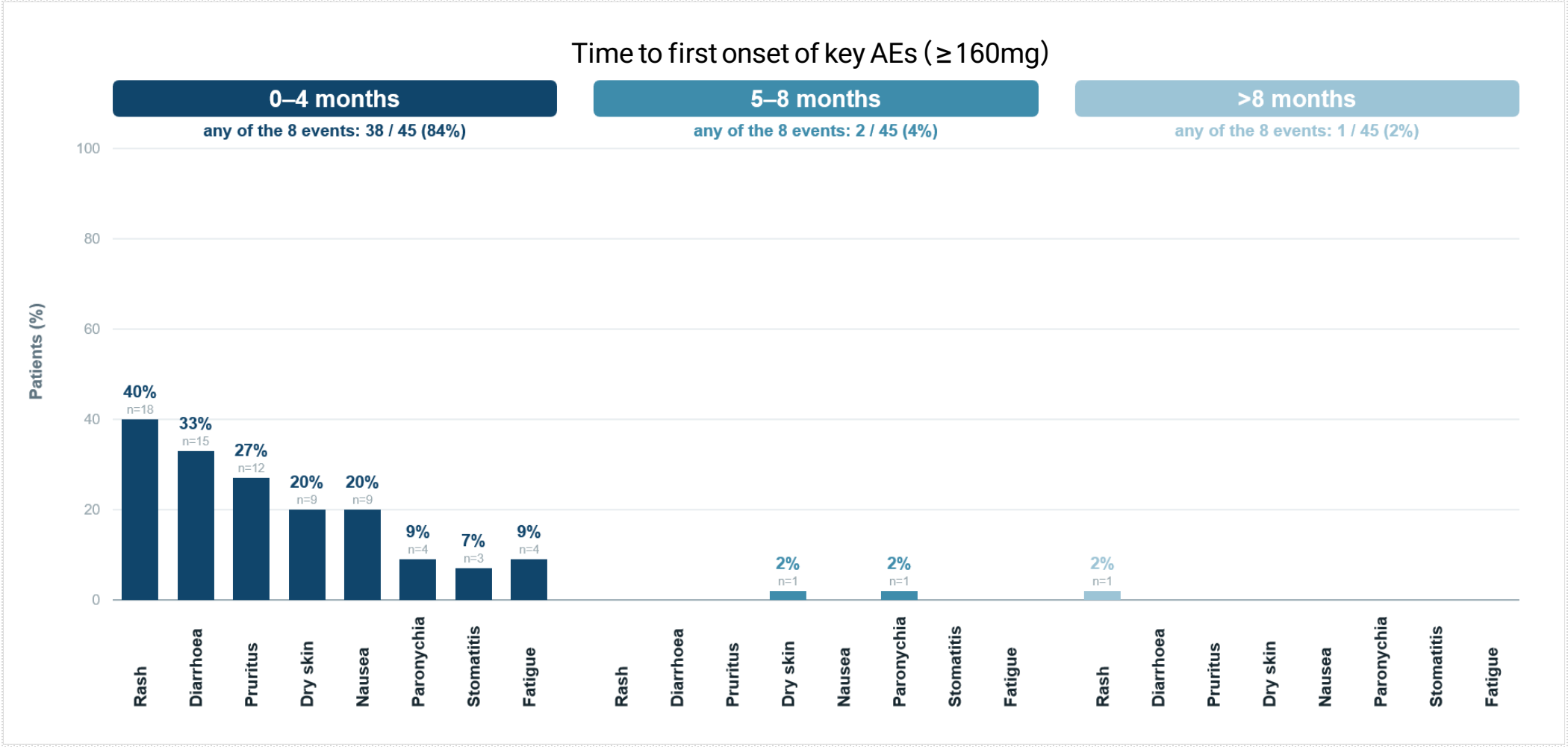
높은 부작용에 따른 병용 요법의 낮은 처방비율 및 실질 투여기간 단축[4,5]



Source: [1]Herbst RS, et al. J Clin Oncol. 2023 Apr 1;41(10):1830-1840, [2]Mok TS, et al. N Engl J Med. 2017 Feb 16;376(7):629-640. [3]Jänne PA, et al. N Engl J Med. 2026 Jan 1;394(1):27-38, [4]Santos E, et al. Journal of Thoracic Oncology, 20S474, [5]Osimertinib (Tagrisso): Therapeutic area: Non-small cell lung cancer: Reimbursement Review [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2025 Jan. Clinical Review.

Safety Profile: Onset Adverse Events

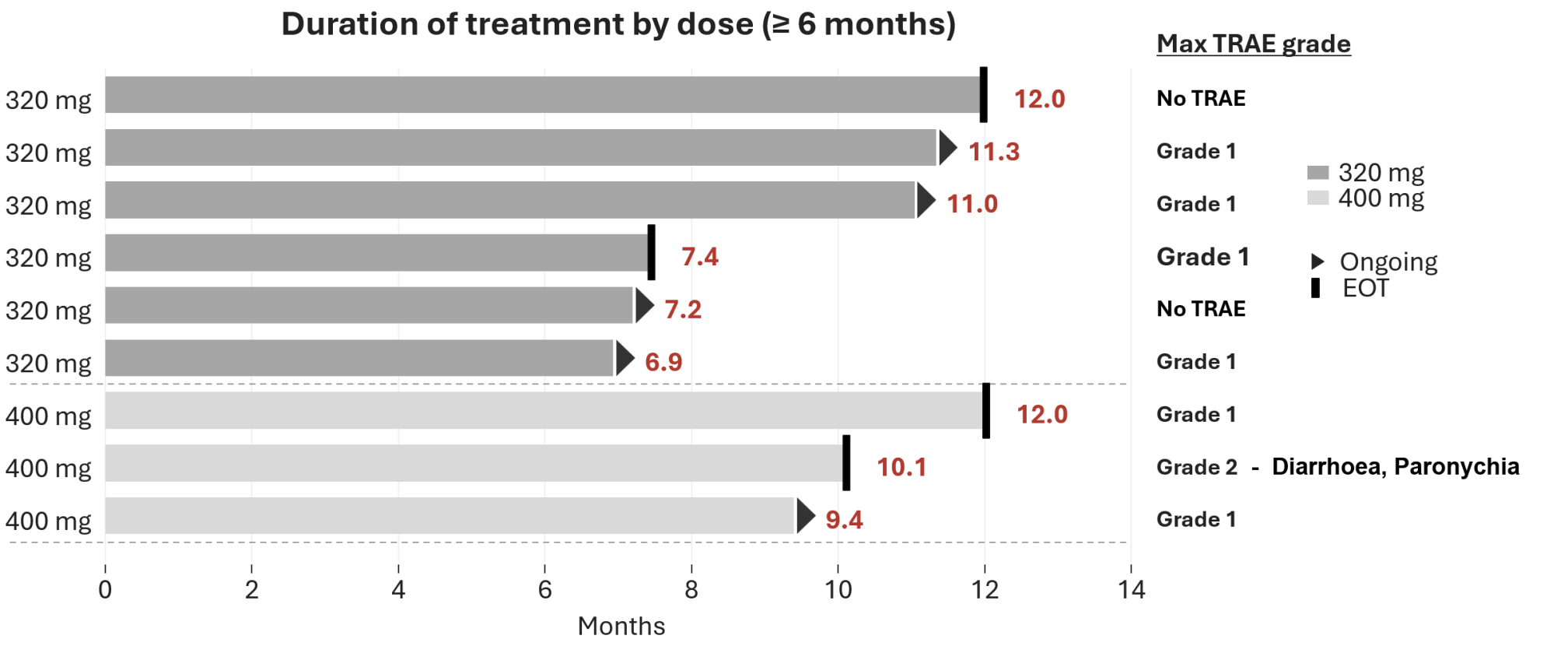
주요 이상반응은 대부분 투여 초기(0~4개월)에 발생하며, 후기 발생은 드묾



Data cut-off July 2, 2026

Safety Profile: Long-Term Exposure

320mg, 400mg을 6개월 이상 투약한 환자에서도 대부분 Grade 1 이상반응만 관찰되었으며, 중대한 이상반응은 없음



우수한 안전성을 기반으로 EGFR Resistance-Negative(unknown) 치료 패러다임 재편

우수한 안전성 프로파일을 기반으로 한 다양한 병용 가능성 존재

표준 치료요법 내성/불응 환자 대상 임상 시험 비교 [1,2,3,4]

EGFR 2L+환자 기본 옵션 (expected)

	VRN11		Dato-Dxd	Chemotherapy	Chemotherapy, Pembrolizumab	Chemotherapy, Amivantamab	Chemotherapy, Amivantamab, Lazertinib	VRN11 +Chemotherapy	
	iPFS	PFS						iPFS	PFS
mPFS (months)	9.1	7.3	4.4	4.2	5.6	6.3	8.3	13.3	11.5
≥ Grade 3 TRAE	2%		25.6%	35%	43.7%	67%	87%	37%	

EGFR 표준 치료 불응 환자 대상으로 VRN11과 세포독성항암제(chemotherapy) 와의 병용요법 진행

Source: [1]Passaro, A. et al. Annals of Oncology, Volume 35, Issue 1, 77 - 90, [2]Jänne PA, et al. N Engl J Med. 2015;372(18):1689-1699, [3]Myung-Ju Ahn et al. J Clin Oncol 43, 260-272(2025), [4]James Chih-Hsin Yang et al., JCO 42, 4029-4039(2024)
PFS, progression-free survival; TRAE, treatment-related adverse event; DCR, disease control rate ※VRN11 병용의 수치의 경우, 두 약물의 단순 합산값

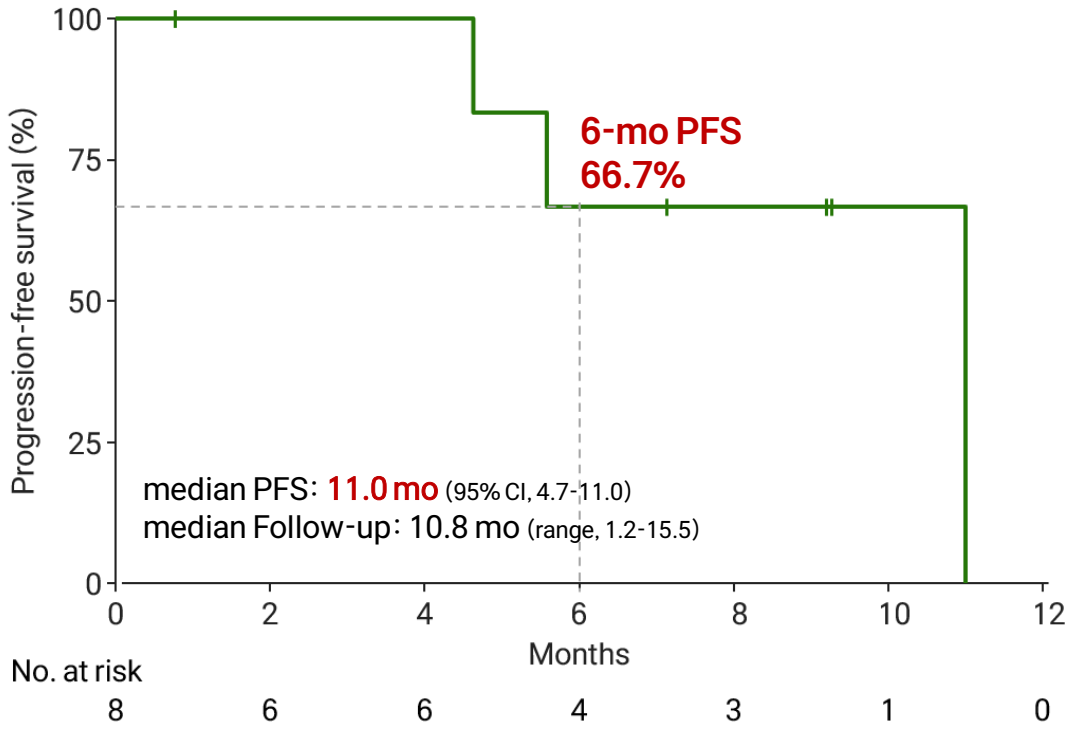


VRN11
EGFR C797S

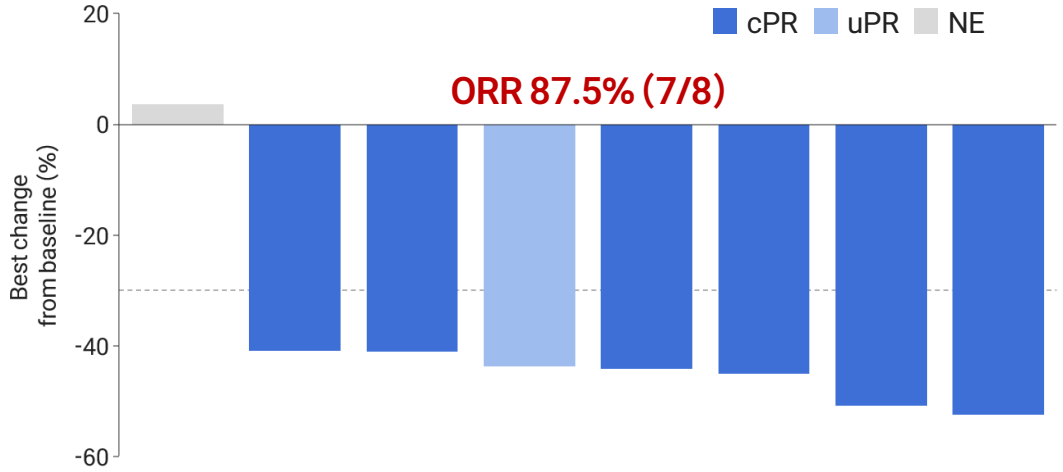
EGFR C797S 변이 환자에서의 치료 효과

유효용량 (≥160mg)을 투약한 모든 EGFR C797S 변이 환자군에서 **무진행 생존기간 11개월** 및 **객관적 반응률 87.5%** 확인(7/8, Partial Response)

Progression-Free Survival



Best Response(≥ 160 mg)



Dose	480mg	320mg	400mg	480mg	240mg	160mg	320mg	320mg
EGFR	L858R /C797S	Del19 /C797S	Del19 /C797S	L858R /C797S /L718V /L792V	Del19 /C797S	Del19 /C797S	Del19 /C797S	L858R /C797S
		Amp.		Amp.	Amp.			Amp.
Prior Lines	2	2	2	6	2	2	1	4

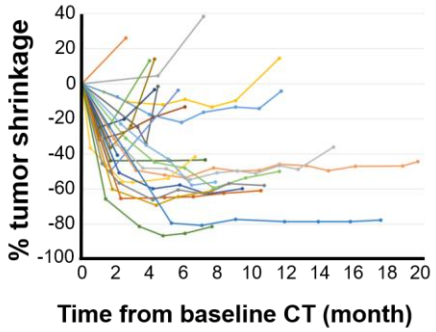
BM, brain metastasis; cPR, confirmed partial response; uPR, unconfirmed partial response; mo, months; NE, not estimable; ORR, objective response rate; PFS, progression-free survival; Amp, Amplification
Data cut-off: October 9, 2026; Median PFS estimate is not mature and subject to change with longer follow-up.
Response-evaluable: patients with C797S treated at ≥ 160 mg and ≥ 1 post-baseline tumor assessment. Median follow-up = time from first dose (C1D1) to data extract for all evaluable patients, regardless of progression, death or discontinuation.

Rapid Achievement of Best Response in EGFR C797S+ Patients

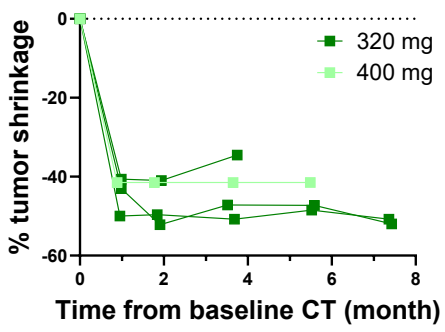
더 많은 선행 치료를 받고, 더 오랜 기간 질병을 경험한 환자군에서 더 빠르고 깊은 종양 감소 확인

Speed of Best Response

Osimertinib in T790M+ patients[1]



VRN11 ≥320mg in C797S+ patients

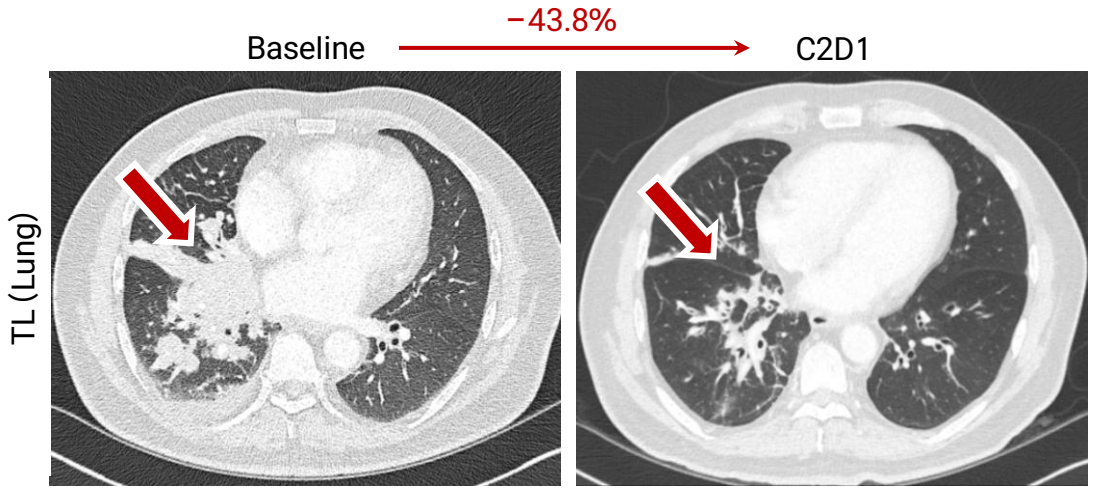


	Depth of Response	Time to Best Response
VRN11 ≥ 160 mg[2] (C797S-positive)	-45.9%	26 days
Osimertinib 80 mg[3] (T790M-positive)	-43.7%	54 days

✓ 강력한 Target Engagement를 바탕으로 후속 치료에서 Osimertinib 대비 빠르고 깊은 종양 감소 확인(26일 vs. 54일, C797-positive vs. T790M- positive)

Case Report

- 63-year-old male · 480 mg · ECOG 0 · 6 prior lines
- Resistance shifted from MET amp to C797S
- C797S after osimertinib + savolitinib
- EGFR VAF (entry): L858R 25.74%, C797S 25.36%, L718V 1.75%, L792V 0.42%
- All 4 target lesions decreased: 2 lung, 2 lymph node



[1]Cho JH, et al. Osimertinib in T790M-positive NSCLC: efficacy and resistance profile. PLoS One. 2019.
[2]Time from first dose to best response in C797S-positive patients who received ≥ 160 mg of VRN11 (1-cycle = 28 days)
[3]Oh DK, et al. PLoS One. 2019;14(1):e0210225, Data shown are for T790M-positive patients

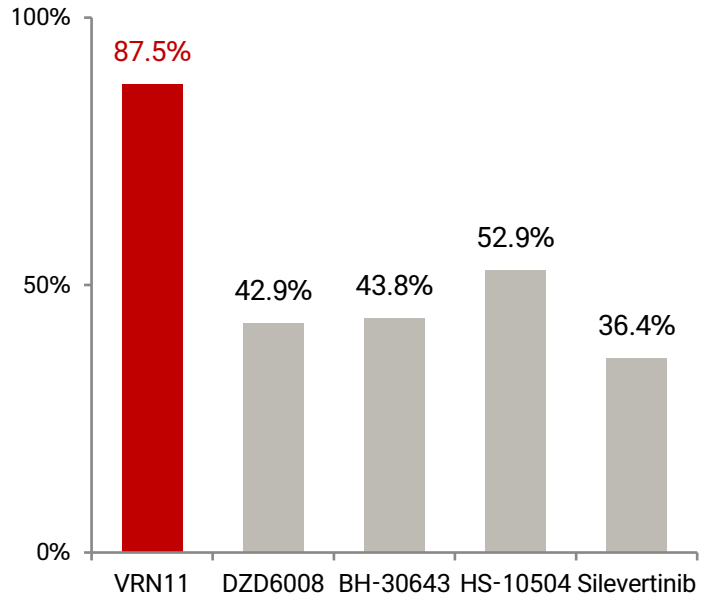
EGFR C797S Competitive Landscape

높은 객관적 반응률(ORR)과 낮은 부작용(Grade≥3)을 통해 효능과 안전성 측면에서 경쟁력 입증

	VRN11	DZD6008	BH-30643	HS-10504		Silevertinib (BDTX-1535)
Clinical study	Ph1	Ph1	Ph1	Ph1		Ph2
ORR	87.5% (7/8)	42.9% (9/21) (60mg)	43.8% (14/32)	300mg	400mg(RP2D)	36.4% (12/33) (200mg)
				31.8%	52.9%	
≥G3 TRAE	2%	*Not reported*	20%	35.3%	65.7%	35%
Dose reduction	7.3%	*Not reported*	16%	0%	42.9%	32%

✓ DZD 6008 Grade ≥3 TRAE: Lymphocyte count decreased 8.3%, Anemia 4.2%, Malaise 4.2%, Fatigue 4.2%, Amylase increased 4.2%
✓ BH-30643 Grade ≥3 TRAE: Bilirubin increased 13%

C797S ORR: VRN11 87.5%
~2-fold higher efficacy
compared to competitors



Sources: Silevertinib: ASCO2026, DZD6008: Wang et al. ASCO 2025 abstract 8616, ASCO2026, NCT06905197. HS-10504: AACR2026, BH-30643: BlossomHill JPM 2026, ASCO 2026, NCT06706076. VRN11: Voronoi internal & ESMO2026.

EGFR Resistance-Positive(C797S) 가속승인 전략

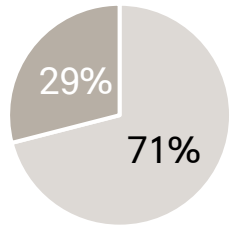
승인된 표적 치료제가 없는 EGFR C797S 변이 영역에서 VRN11의 독보적 효능 및 내약성 기반 가속승인 추진
3% 수준의 Driver 변이로 USD 1B 글로벌 매출 예상

EGFR C797S 변이 발생 비율[1,2]

✓ 1차 치료 이후 C797S 발생 비율

타그리소 단독/병용 처방 비율

C797S 발생 비율 3%

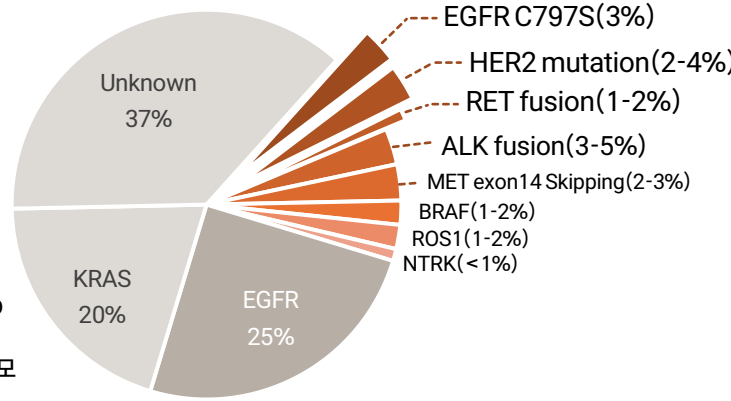


C797S 발생 비율 10%

monotherapy
combination therapy

✓ 1차 치료 이후 뿐 아니라,
2차 이상(2L+) 후속 치료 라인에서도 C797S 변이 지속 발생

비소세포폐암 희귀 Driver 변이 표적 TKI 상업성 비교(Commercial Potential)



※Precedent Transactions
Blueprint Medicines → Zai Lab
전임상 단계에서 중화 판권 기술이전
계약금 2,500만 달러, 총 6억 달러 규모
(Nov. 2021)

표적	발생 비율	대표 약물명	가속 승인 연도	Annual Sales
EGFR C797S	3%	VRN11	2027-2028 (expected)	$1B(expected)
HER2 mutation	2-4%	Zongertinib (Hernexeos)	2025	$1B(estimated)
ALK fusion	3-5%	Lorlatinib (Lorbrena)	2015	$1.2B
RET fusion	1-2%	Selpercatinib (Retevmo)	2020	~$0.5B

Source: [1]Santos E, et al. Journal of Thoracic Oncology, 20S474, [2]WCLC2024



VRN11
Clinical Development Strategy

VRN11 Phase 1/2 Expansion

Ph1/2 Dose selection

✓ Low dose 320mg

High dose TBD

Ph1/2 Cohort

Move to First Line (1L)

1L common EGFR
Treatment-naïve
Enrolling Cohort B

1L atypical EGFR
Treatment-naïve
Enrolling Cohort D

Overcome Resistance after 3G TKI

C797X
Common + C797X
Enrolling Cohort A

CNS metastases
Lesion ≥ 5 mm and/or LM
Cohort E

Combination
Post-3G TKI; BOIN design
Cohort G

- **CNS lesions, C797S−** (≥ 160 mg, n=20; **85% post-3G TKI**): 6-/12-mo iPFS 79.8%/49.9% (osimertinib, T790M−, post-1·2G TKI: 31% at 6 mo); mPFS 9.1 mo.
- **C797S+** (≥ 160 mg): 7/8 with > 40% target lesion reduction; median time to best response 26 days (osimertinib, T790M+: 54 days); mPFS 11.0 mo.
- **C797S−** (≥ 320 mg, n=17; **82% post-3G TKI**): mPFS 7.3 mo (osimertinib, post-1·2G TKI: **2.8–4.1 mo**).
- **Well tolerated**: TRAEs mostly G1–2 (any 61%, ≥ G3 2%); no DLT or treatment-related discontinuation.
- Activity, observed almost entirely after 3G TKI progression, is consistent with estimated target engagement ~4× (systemic) and ~40× (CNS; $Kp_{,uu,CSF}$ 2.0 vs 0.22) that of osimertinib 80 mg.

VRN11 임상 개발 전략

우수한 효능·안전성·뇌 투과율 데이터를 바탕으로, EGFR 변이 폐암 전반의 미충족 의료 수요 해결을 목표로 하는 임상 개발 전략

2차 치료(2L+) 데이터에 기반한 1차 치료(1L)로의 진입/확장

1차 치료(1L) 패러다임의 전환

	VRN11 (expected)	Osimertinib[1,2]
Depth of response	≥-60%(Low) ≥-70%(High)	-50%
CNS CR	≥70%	16%
PFS	40~60m(Low) ≥7y(High)	18.9
≥Grade 3 TRAEs	Low	13%

가속승인 기대(2L+)

Brain Metastasis

Osimertinib* 대비 우월한 임상 데이터 확인:
Kp,uu,CSF : 0.2 vs 2.0
CNS PFS: 3.5 vs **9.1**개월)

Resistance Positive(+)
C797S

ORR **87.5%** (7/8, ≥160mg)
PFS **11**개월

Resistance Negative(-)
Unknown Resistance

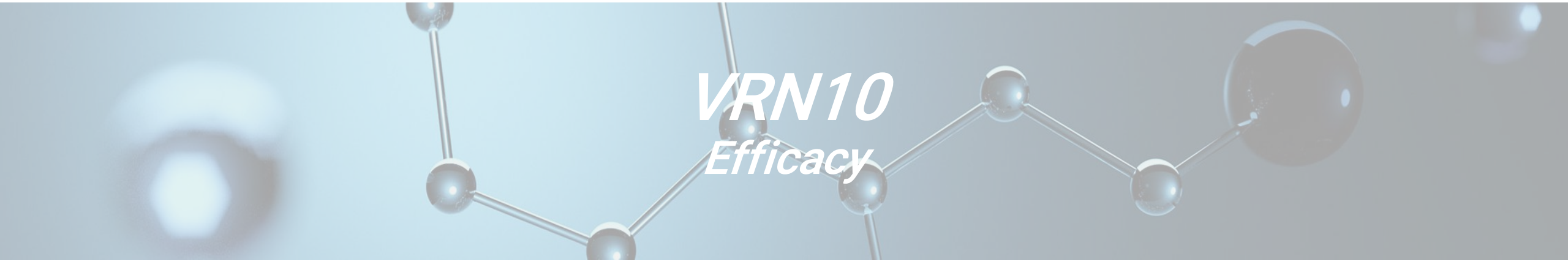
PFS **7.3** 개월
압도적 안전성 확인(≥Grade 3 TRAEs **2%**)

Data cutoff October 9,2026
Source: [1]Soria JC, et al. N Engl J Med. 2018 Jan 11;378(2):113-125. [2]Jänne PA, et al. J Clin Oncol. 2024 Mar 1;42(7):808-820.



Creating Novel Therapeutics
For patients with Excellent Experts
In Drug Design

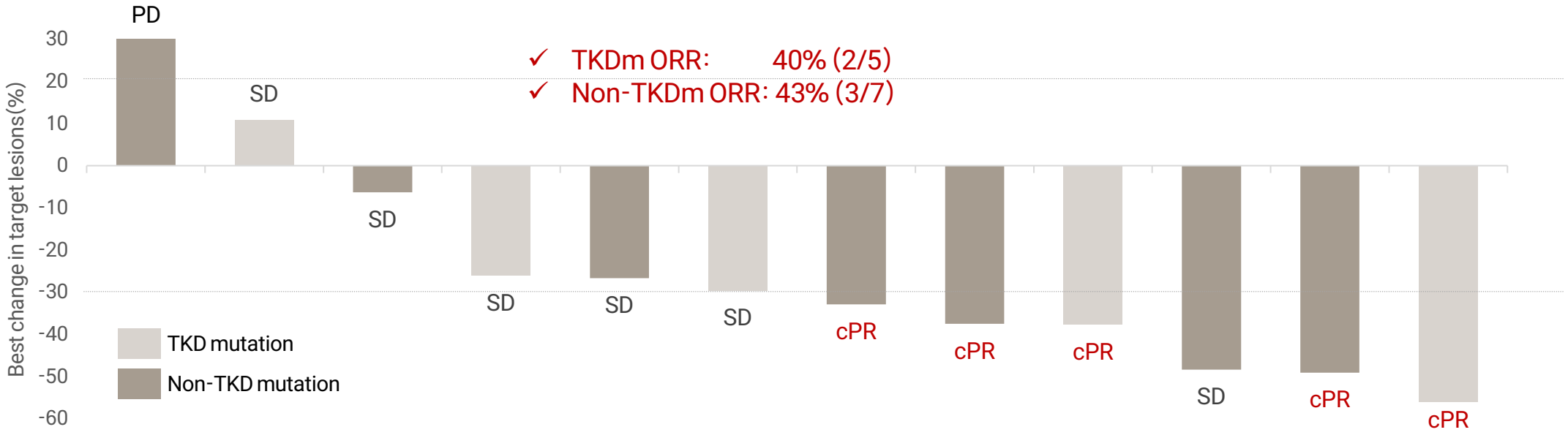
VRN10
HER2 Targeted Therapy



VRN10

Efficacy

Clinical results (1) HER2 mutation patients



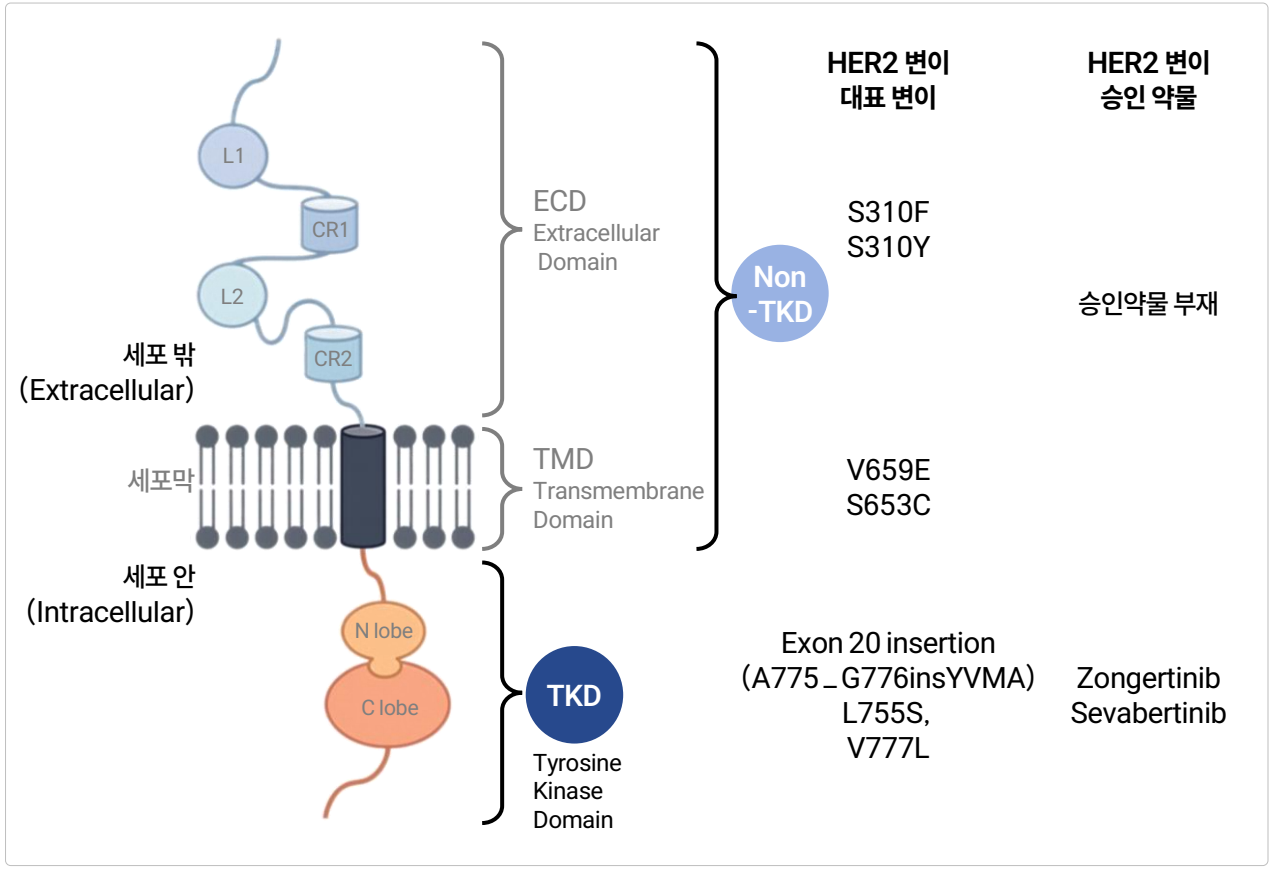
HER2 mutation	R678Q	G727A	S310Y	L755S	S310F	V777L	S310F	S653C	L755P	V659E	S310Y	YVMA
Primary site	CBDC	UC	GC	CRC	PDAC	BC	HNC	AVC	NSCLC	RCC	NSCLC	NSCLC
Prior HER2-TXs	-	-	-	-	TUC H	**T-DXd**	ZAN	-	**T-DXd**	-	H NER **T-DXd**	SEV ELVN **T-DXd**
No. prior systemic TXs	2	4	1	2	3	7	1	1	3	2	3	7

Evaluable patients had at least one post-baseline tumor assessment.
Abbreviations:
Treatments: ELVN, ELVN-002; H, trastuzumab; HP, trastuzumab plus pertuzumab; LAP, lapatinib; NER, neratinib; SEV, sevabertinib; T-DM1, trastuzumab emtansine; T-DXd, trastuzumab deruxtecan; TUC, tucatinib; ZAN, zanidatamab; ZON, zongertinib.
Tumor types: AVC, ampulla of Vater cancer; BC, breast cancer; CBDC, common bile duct cancer; CRC, colorectal cancer; CxCa, cervical cancer; EC, esophageal cancer; EMC, endometrial cancer; GC, gastric cancer; HNC, head and neck cancer; mBC, metastatic breast cancer; mGC, metastatic gastric cancer; NSCLC, non-small-cell lung cancer; PC, pancreatic cancer; RCC, renal cell carcinoma; SGC, salivary gland cancer; SKC, skin cancer; UC, urothelial carcinoma.

HER2 Domain-Specific Mutation & Efficacy Profile

HER2 돌연변이 고형암 환자군에서 치료 효과 확인

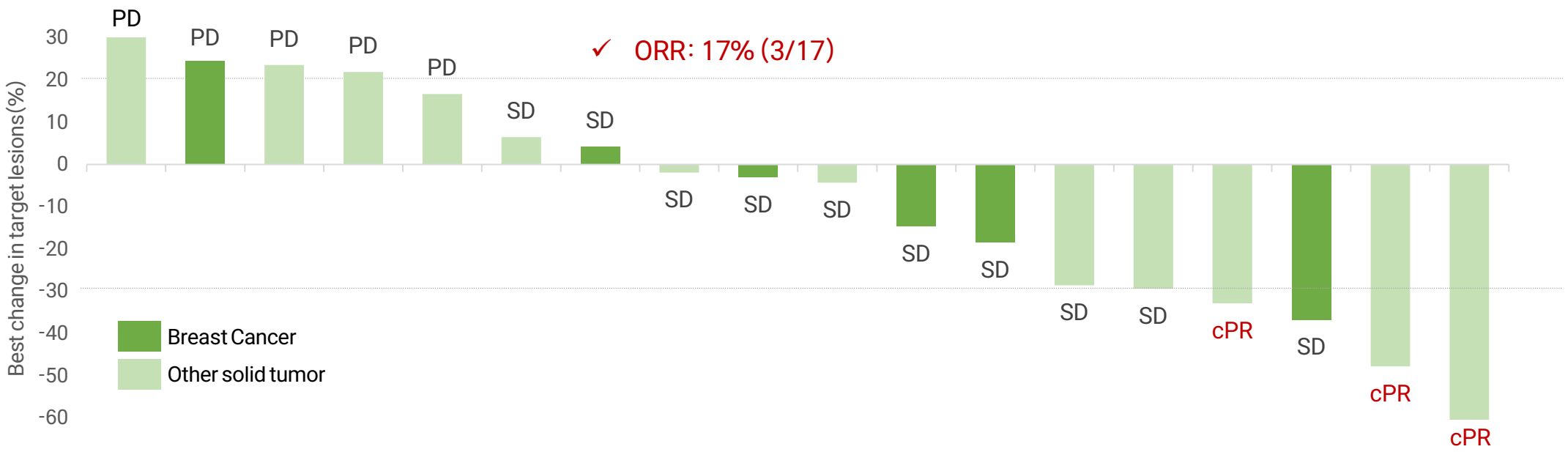
HER2 도메인 분류 및 변이 현황 (Structural Domains of HER2)



TKI	VRN10		Zongertinib[1]			Sevabertinib[2]	
Phase	1A		1A		1B	1B	
Indication	All	NSCLC	All	NSCLC	NSCLC	NSCLC	
Prior Tx		ADC			ADC		ADC
All	42% (5/12)	100% (3/3)	31% (32/105)	35% (15/43)		64% (52/81)	38% (21/55)
TKD	40% (2/5)	100% (2/2)		38% (9/24)	71% (53/75)	48% (15/31)	70% (51/73)
Non-TKD	43% (3/7)	100% (1/1)			30% (6/20)		14% (1/7)

[1]Beamion LUNG-1 (NCT04886804)
[2]SOHO-01 (NCT05099172)

Clinical results (2) HER2 positive patients



HER2 status	IHC 3+	IHC3+ ISH+	IHC2+ ISH+	IHC3+	IHC3+	IHC2+ ISH+	IHC3+ ISH+	IHC3+	IHC3+ Amp	IHC3+	IHC3+ ISH+	IHC2+ ISH+ Amp	IHC3+	IHC3+ Amp	IHC3+ISH + (S310F)
Primary site	EC	BC	GC	GC	EMC	GC	BC	GC	BC	SGC	BC	BC	SKC	CRC	HNC
Prior HER2-TXs	H	HP T-DXd ZAN	H T-DXd	H T-DXd	T-DXd	H T-DXd	H T-DM1 T-DXd	H T-DXd	H LAP T-DM1 T-DXd	H T-DM1 ZON	HP TUC T-DXd	HP T-DXd	H T-DXd	-	ZAN
No. prior systemic TXs	1	3	5	4	2	3	6	3	10	4	7	2	5	2	1

Evaluable patients had at least one post-baseline tumor assessment.
Abbreviations:
Treatments: ELVN, ELVN-002; H, trastuzumab; HP, trastuzumab plus pertuzumab; LAP, lapatinib; NER, neratinib; SEV, sevabertinib; T-DM1, trastuzumab emtansine; T-DXd, trastuzumab deruxtecan; TUC, tucatinib; ZAN, zanidatamab; ZON, zongertinib.
Tumor types: AVC, ampulla of Vater cancer; BC, breast cancer; CBDC, common bile duct cancer; CRC, colorectal cancer; CxCa, cervical cancer; EC, esophageal cancer; EMC, endometrial cancer; GC, gastric cancer; HNC, head and neck cancer; mBC, metastatic breast cancer; mGC, metastatic gastric cancer; NSCLC, non-small-cell lung cancer; PC, pancreatic cancer; RCC, renal cell carcinoma; SGC, salivary gland cancer; SKC, skin cancer; UC, urothelial carcinoma.

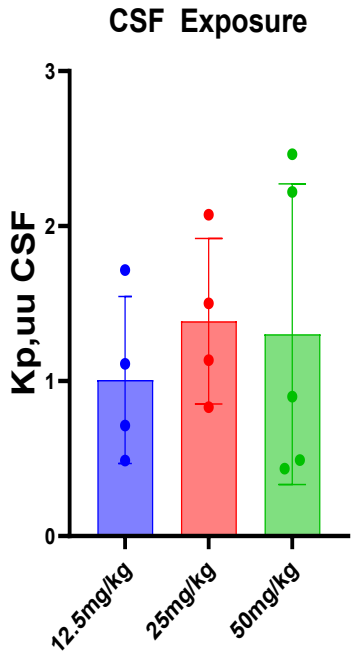


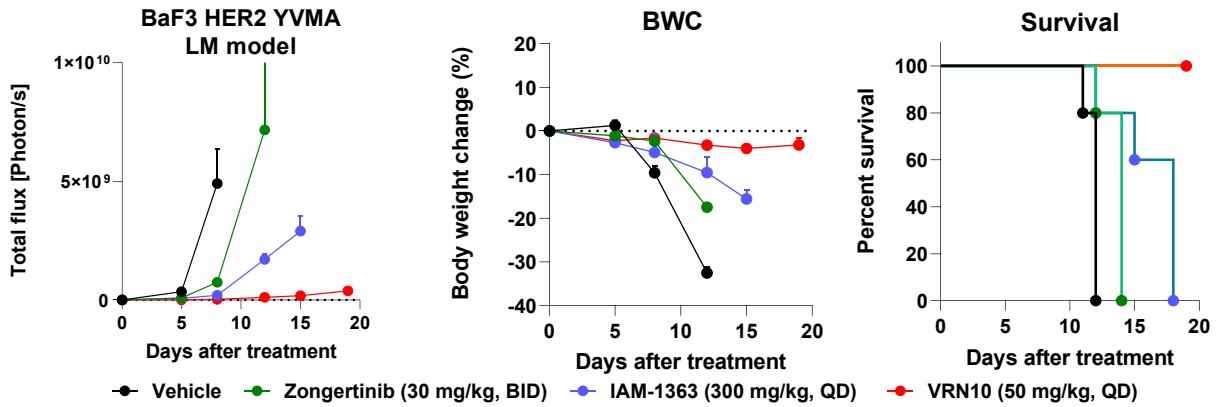
VRN10

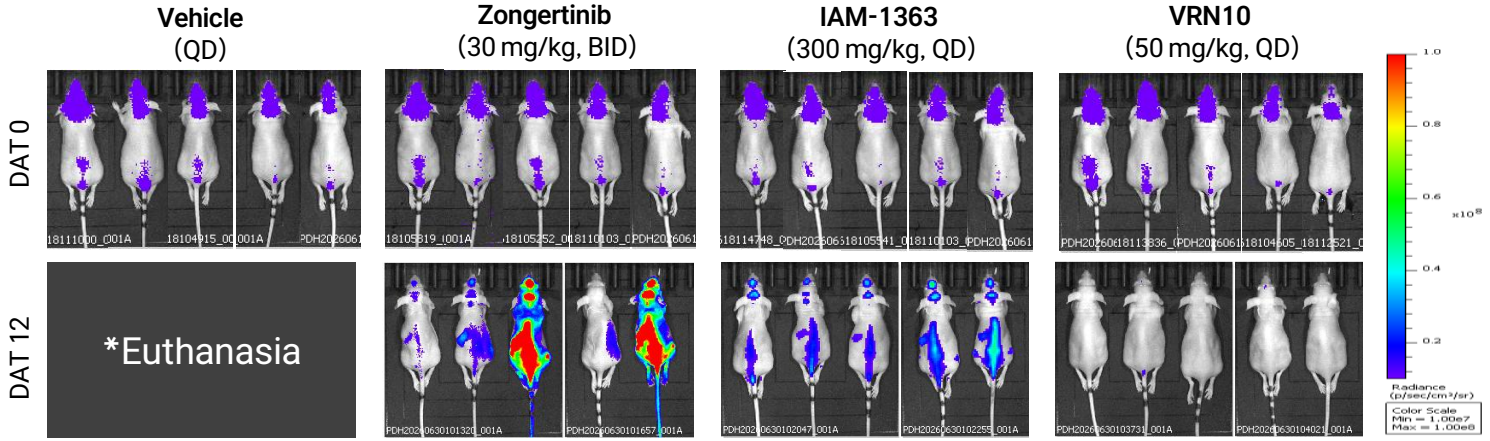
Intracranial Response

CNS Activity: HER2 YVMA Intracranial Model (Leptomeningeal metastasis)

VRN10, 마우스에서 **우수한 뇌 투과력** 확인(Kp,uu,CSF ~1)
HER2 변이 비소세포폐암의 대부분을 차지하는 YVMA 변이 두개내 모델에서 경쟁 약물 대비 뛰어난 항종양 효능 확인



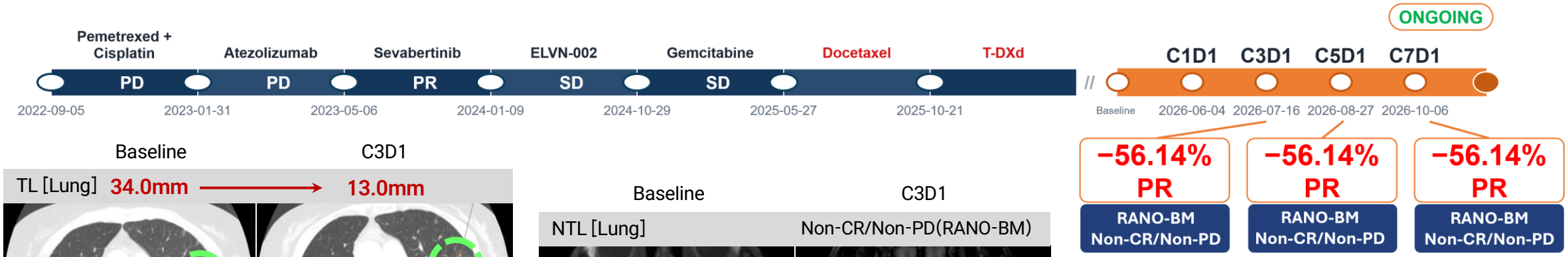


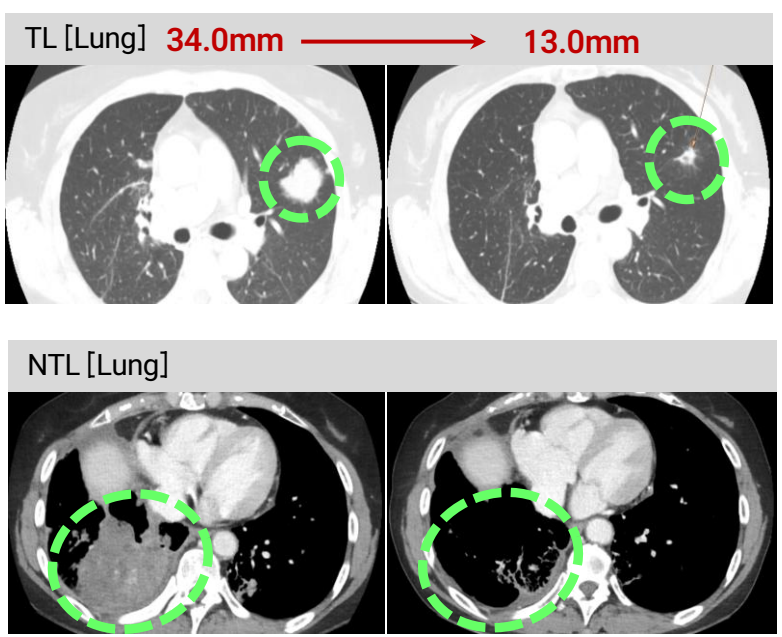


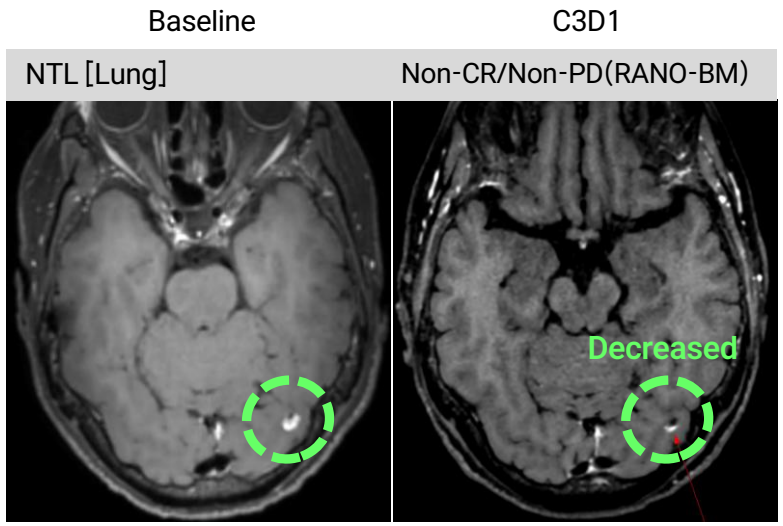
Source: WCLC2026

Clinical Case Study：Intracranial Response

Case1：HER2 A775_G776insYVMA · NSCLC



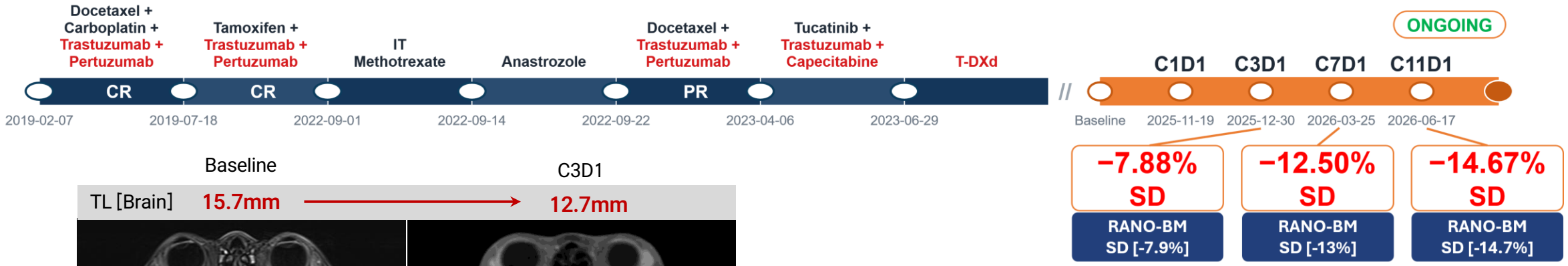


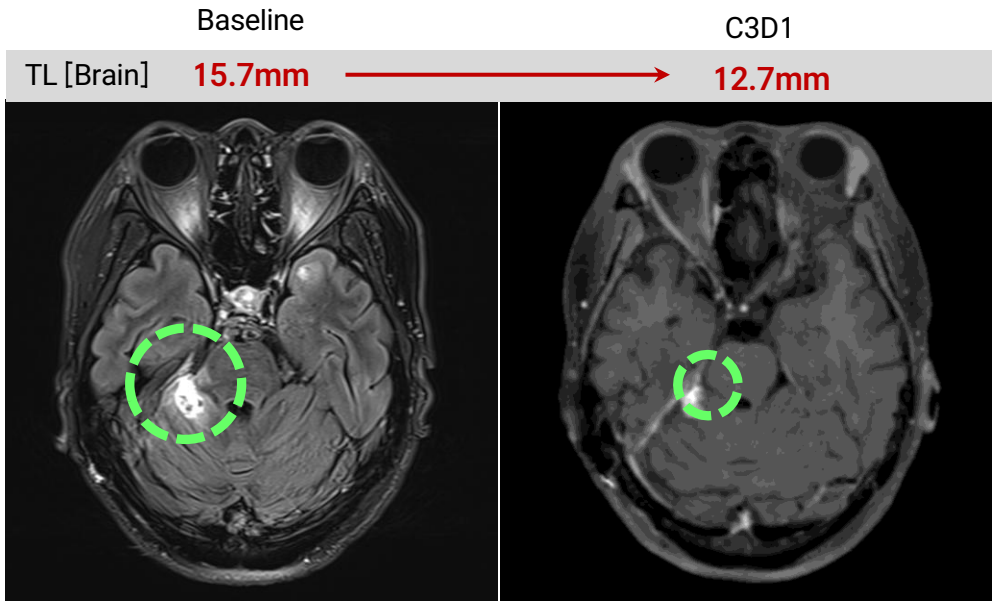


- 2 Lung TL PR achieved at First Tumor Assessment (-56.1%)
- Deep partial response following relapse on sevabertinib, ELVN-002, and T-DXd
- Brain NTL also decreased (RANO-BM：Non-CR/Non-PD)

Clinical Case Study：Intracranial Response

Case2：HER2 positive Breast Cancer





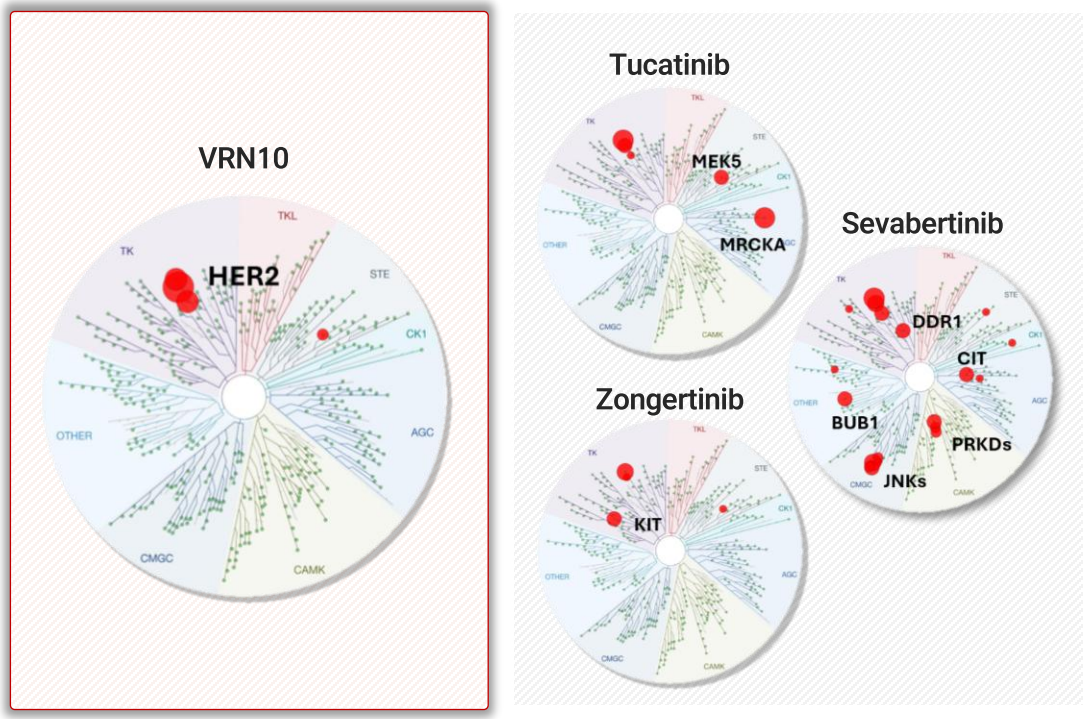
- Heavily pretreated：7 prior systemic regimens, including 5 HER2-directed therapies (prior T-DXd)
- Brain target lesion reduced；non-target lesions stable (SD per RANO-BM)
- Duration of treatment：10.6 months (ongoing)


VRN10
Safety

경쟁 약물 대비 뛰어난 선택성

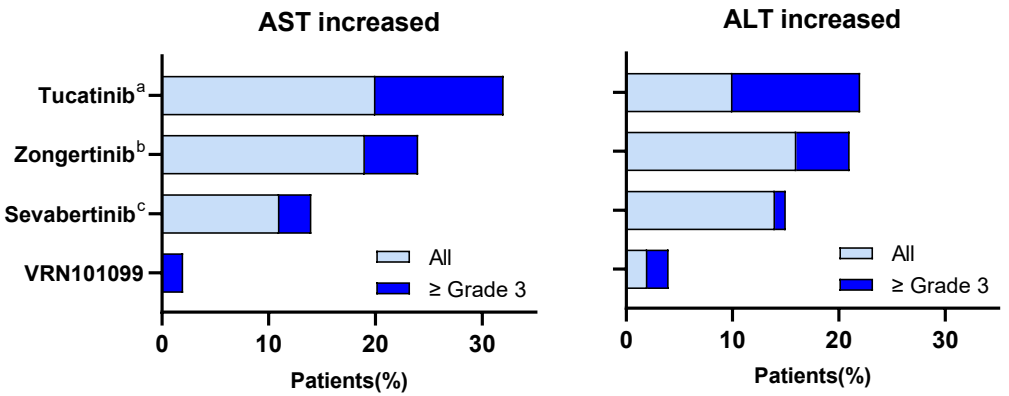
경쟁 약물 대비 뛰어난 선택성으로, 간독성 및 심독성 발생 우려 낮음

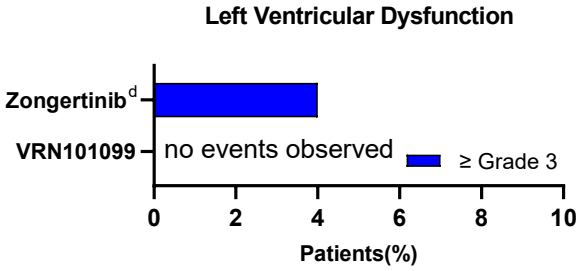
VRN10 선택성(Selectivity)



✓ Shared hepatotoxicity, divergent off-target toxicities
: a selectivity issue across HER2 TKIs.

경쟁약물 대비 낮은 간독성 및 심독성



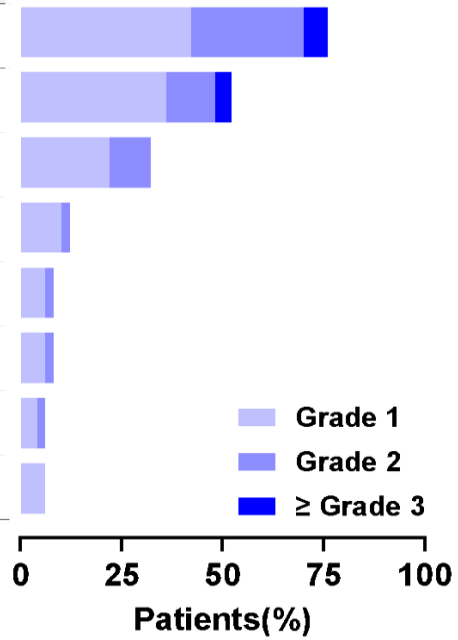


Source: a. Borges VF, Ferrario C, Aucoin N, et al. Tucatinib Combined With Ado-Trastuzumab Emtansine in Advanced ERBB2/HER2-Positive Metastatic Breast Cancer: A Phase 1b Clinical Trial. JAMA Oncol. 2018;4(9):1214-1220. doi:10.1001/jamaoncol.2018.1812
b. Heymach JV, Ruiter G, Ahn MJ, et al. Zongertinib in Previously Treated HER2-Mutant Non-Small-Cell Lung Cancer. N Engl J Med. 2025;392(23):2321-2333. doi:10.1056/NEJMoa2503704
c. Le X, Kim TM, Loong HH, et al. Sevabertinib in Advanced HER2-Mutant Non-Small-Cell Lung Cancer. N Engl J Med. 2025;393(18):1819-1832. doi:10.1056/NEJMoa2511065
d. Heymach JV, Opdam F, Barve M, et al. HER2-Selective Tyrosine Kinase Inhibitor, Zongertinib (BI 1810631), in Patients With Advanced/Metastatic Solid Tumors With HER2 Alterations: A Phase Ia Dose-Escalation Study. J Clin Oncol. 2025;43(11):1337-1347. doi:10.1200/JCO-24-01727

Safety Profile

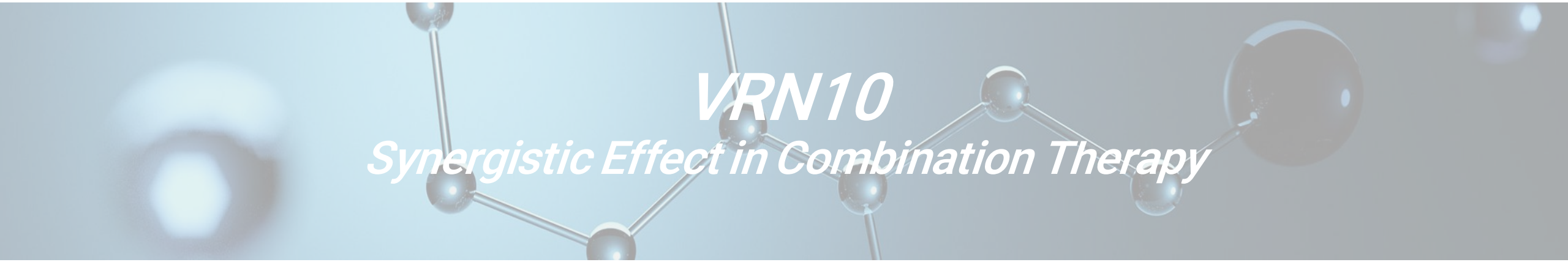
TRAEs occurring in ≥5% of patients are shown.

Drug-related AE	VRN10, 80 – 480mg (n=50)	
	All	≥ Grade 3
Any	38 (76%)	3 (6%)
Diarrhea	26 (52%)	2 (4%)
Nausea	16 (32%)	0
Vomiting	6 (12%)	0
Decreased appetite	3 (6%)	0
Rash	4 (8%)	0
Fatigue	3 (6%)	0
Stomatitis	3 (6%)	0



- 모든 용량 수준에서 전반적으로 양호하고 관리 가능한 안전성 프로파일 확인
- 설사 발생 시 로페라미드(loperamide)를 필요에 따라 투여하여 효과적으로 관리 가능
- 최대내약용량(MTD)에 도달하지 않음
- 현재 560mg 투약 진행 중

Combined term, includes rash, rash maculopapular, exfoliative rash
Abbreviations: adverse event; TRAE; AE, adverse event; AST, Aspartate Aminotransferase; ALT, Alanine Aminotransferase.

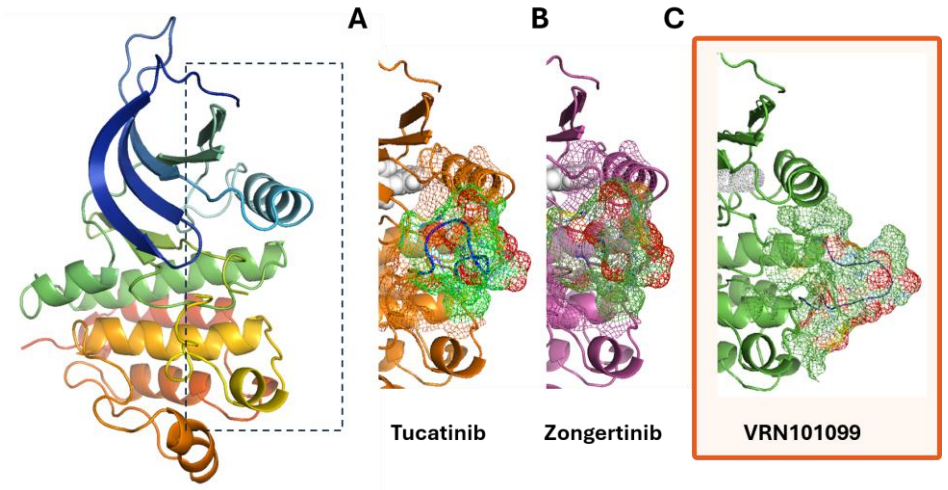


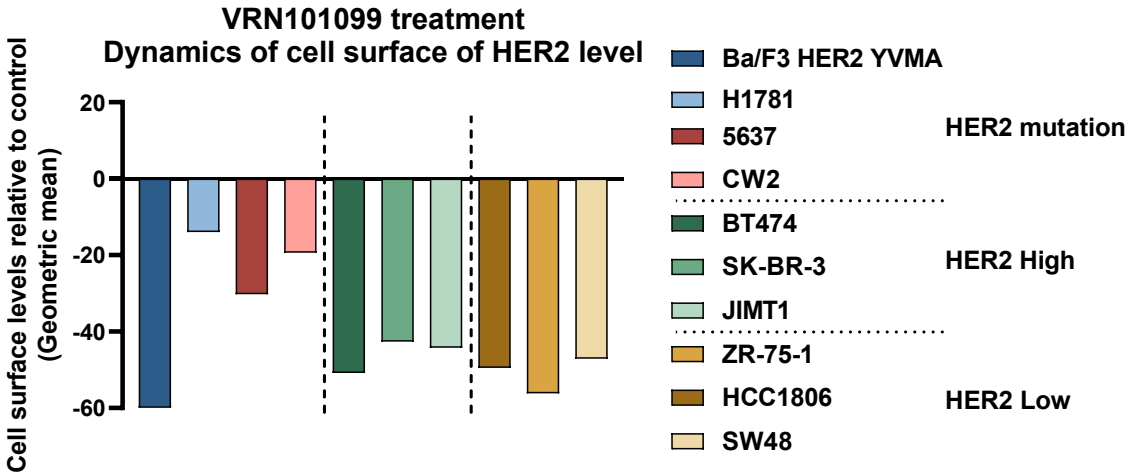
VRN10

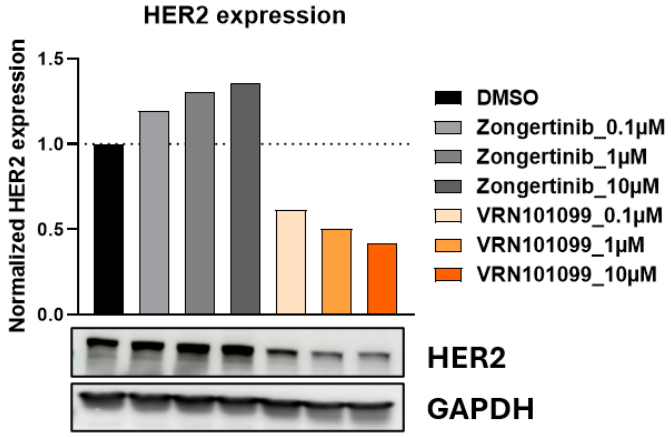
Synergistic Effect in Combination Therapy

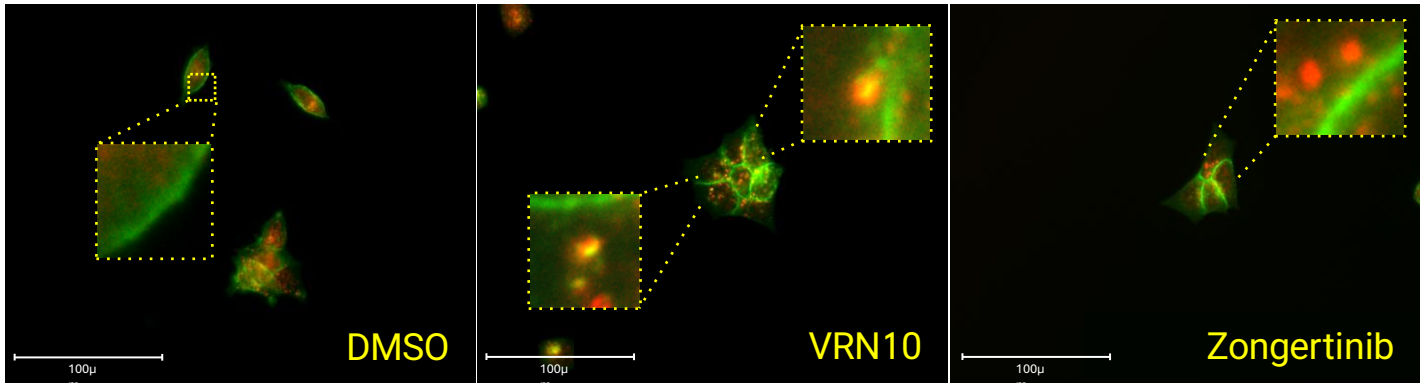
Unique Binding Mode and On-Target Degradation

차별화된 결합을 통해 HER2 수용체의 세포 내재화 및 분해 유도



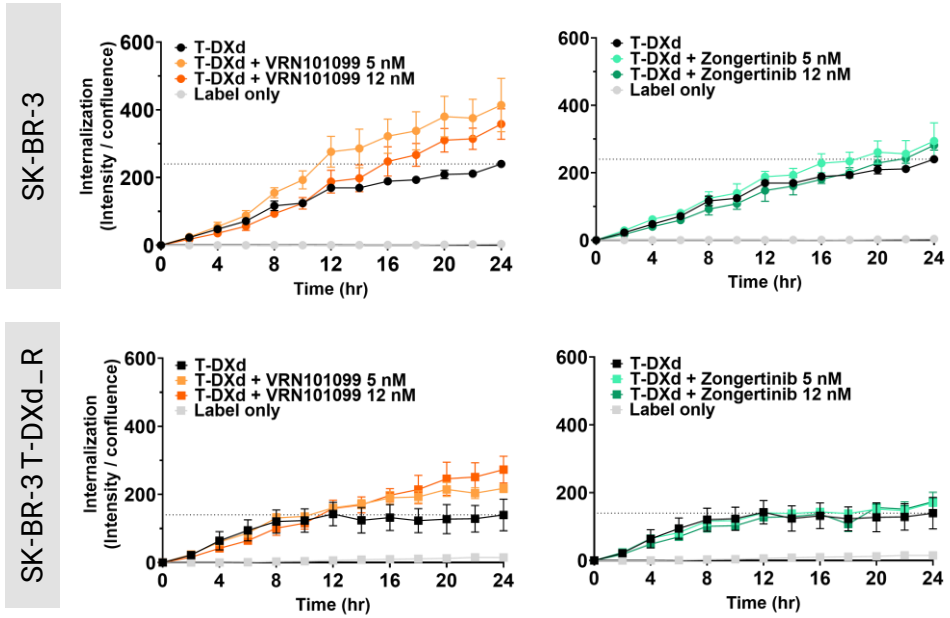






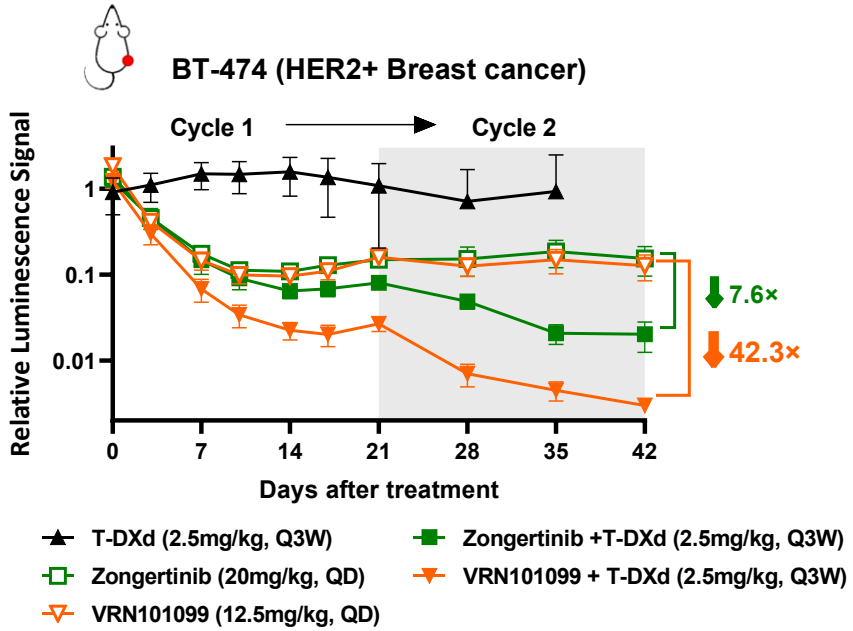
VRN10 induced HER2 internalization(vs. Zongertinib)

Induced HER2 Internalization and Enhanced T-DXd Uptake



✓ 병용 시, 농도 의존적(5 nM, 12 nM)으로 HER2 내재화 신호 지속 증가
✓ HER2 Internalization 촉진을 통한 T-DXd Uptake 증대

Superior In Vivo Tumor Regression of T-DXd Combination



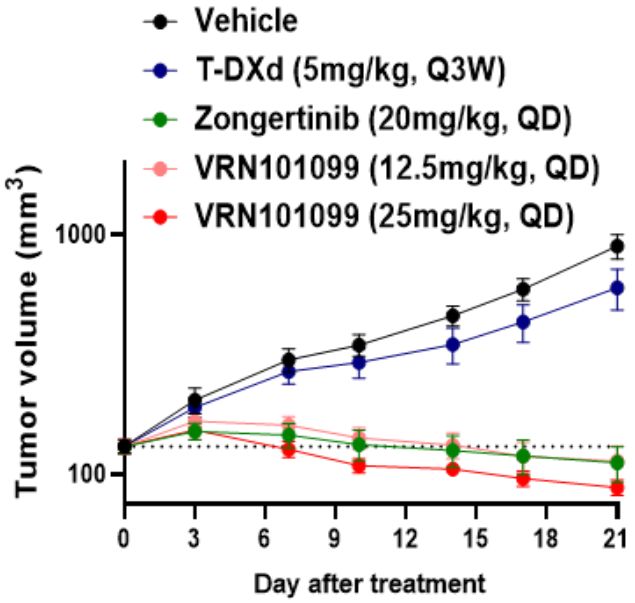
✓ Zongertinib 병용군 대비 월등한 종양 억제력

In vivo anti-tumor efficacy in T-DXd resistance model

T-DXd 내성 종양 세포 기반의 두개내(Intracranial , IC) 및 피하(Subcutaneous , SC)모델에서 효능 확인

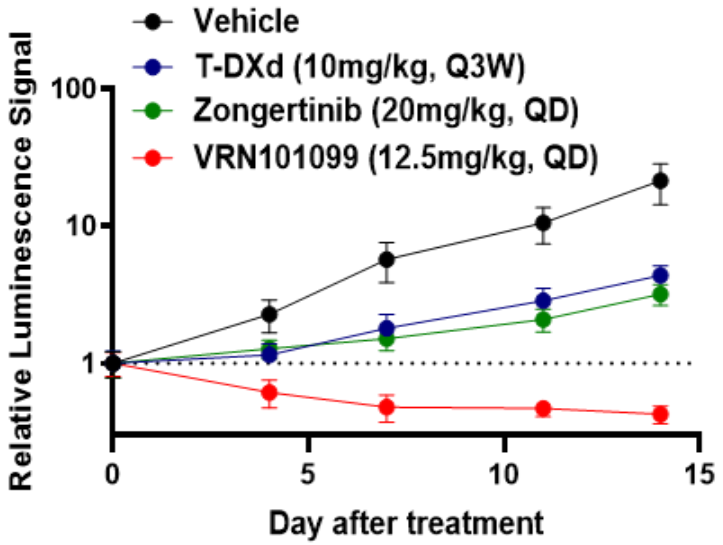


AKR1C Overexpressing(OE) T-DXd resistant
NCI-N87

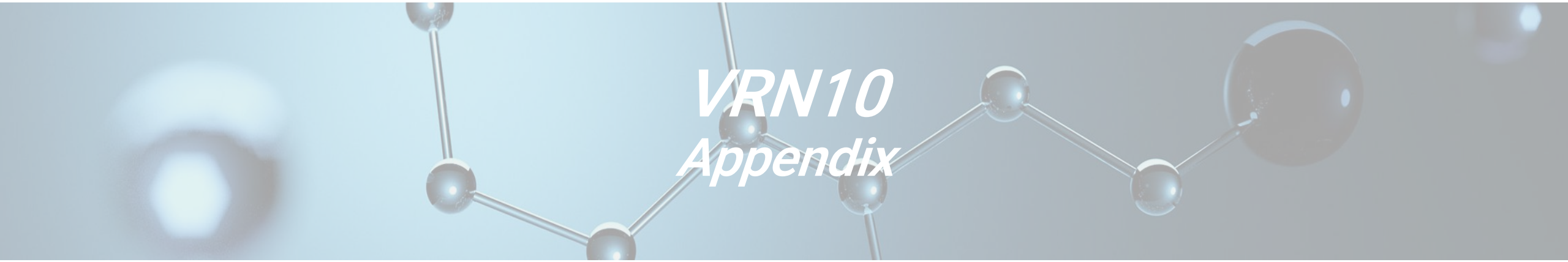




BCRP Overexpressing(OE) T-DXd resistant
SK-BR-3



✓ AKR1C has been reported to mediate metabolism of the T-DXd payload DXd.
✓ Both **DXd and Zongertinib are substrates of BCRP**, whereas **VRN10 is not.**



VRN10
Appendix

Case Report: HER2-Mutant Patients(1)

Patient A

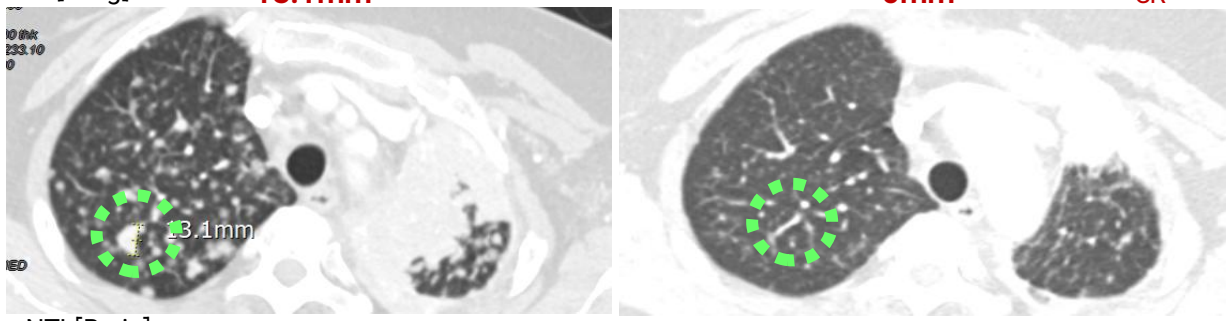
56 Female · 160 mg · Lung Cancer

HER2 S310Y

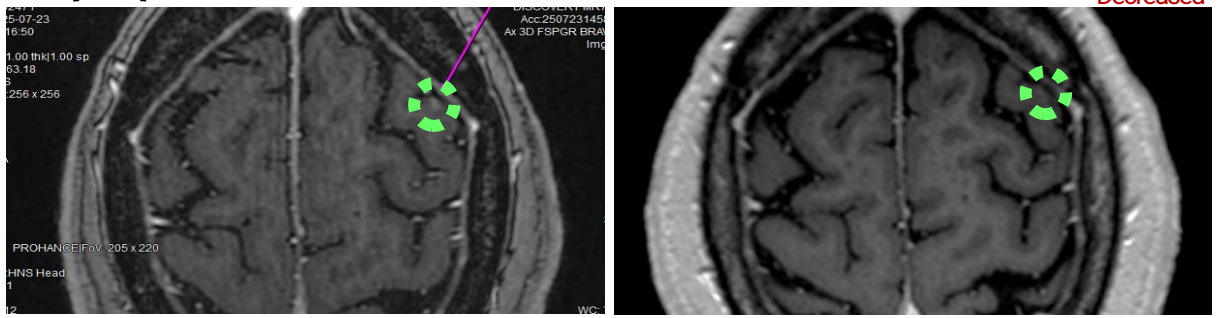
pembrolizumab+pemetrexed+cisplatin SD → **trastuzumab+neratinib** SD → **T-DXd** SD → **VRN10 PR**

TL[Lung]

Baseline **13.1mm** ----------→ C3D1 **0mm** "CR"



NTL[Brain] "Decreased"



- Prior therapies, including T-DXd, all reached only stable disease
- Achieved PR at C5D1 with continued response by -49.1% at C14D1
- Overall PR with sequential CR in TLs: Lung at C3D1 and Breast at C14D1

Patient C

46 Female · 160 mg · Breast Cancer

HER2 V777L

palbociclib+letrozole **PR** → fulvestrant Unknown → fulvestrant+alpelisib **PD** → everolimus+exemestane **SD** → capecitabine **PR** → paclitaxel **PR** → T-DXd **PR** → **VRN10 SD**

- Anti-Tumor activity in heavily pre-treated setting (≥7 prior Tx)
- Tumor response by RECIST v1.1: **SD** (-29.7% in Liver TL at C5D1)
- Discontinued due to non-TL PD

Patient D

72 Male · 80 mg · **Pancreatic** Cancer

HER2 S310F

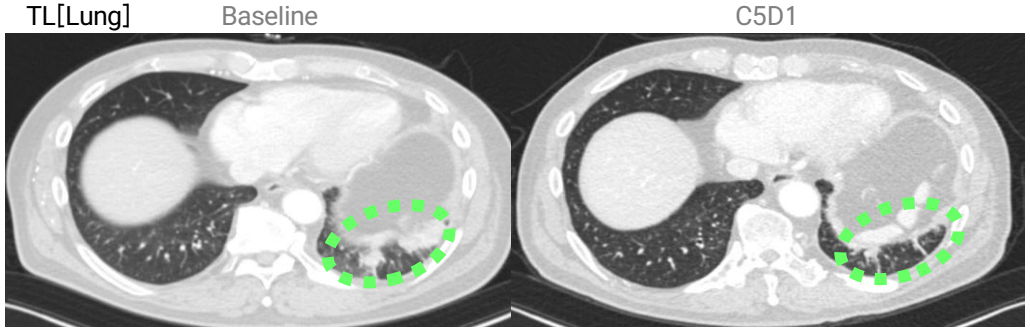
FOLFIRINOX Unknown → nab-paclitaxel+gemcitabine Unknown → trastuzumab+tucatinib **SD** → **VRN10 SD**

- Tumor response by RECIST v1.1: SD (-26.7% shrinkage in Stomach at C3D1)
- Tx interrupted for ~3 weeks due to underlying disease
- Discontinued to **subject withdrawal**

Case Report: HER2-Mutant Patients(2)

Patient B 60 Male · 320 mg · Lung Cancer — **HER2 L755P**

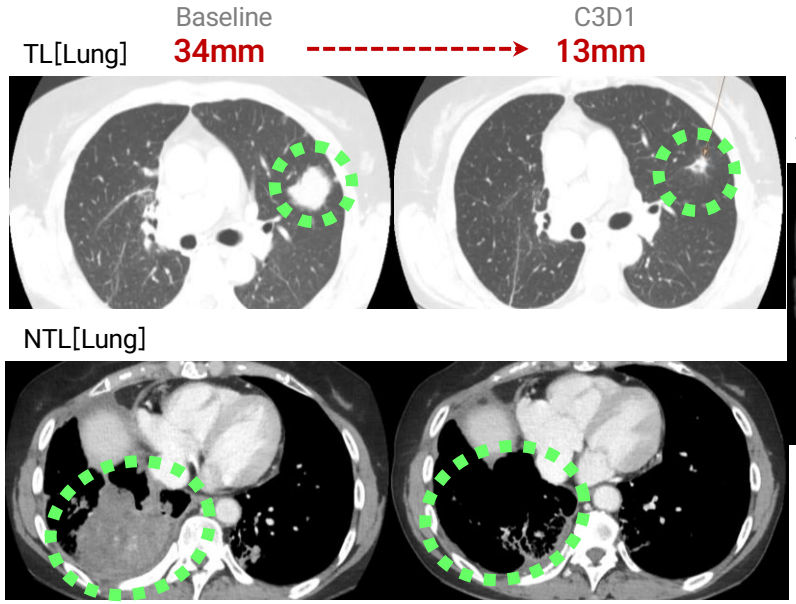
MEDI5752(anti-PD-1xCTLA-4 bispecific antibody) + pemetrexed + carboplatin **SD** → pembrolizumab + pemetrexed + carboplatin **PD** → T-DXd **PR** → **VRN10 PR**



- PR maintained with VRN10 following prior T-DXd (17 months)
- Overall PR with -35.8% tumor reduction in 2 Lung TL at C5D1
- **G3 diarrhea resolved** within a week via anti-diarrheal regimen

Patient E 62 Female · 240 mg · Lung Cancer — **HER2 A775_G776insYVMA**

pemetrexed + cisplatin **PD** → atezolizumab **PD** → sevabertinib **PR** → ELVN-002(HER2 TKI) **SD** → gemcitabine **SD** → docetaxel **PD** → T-DXd **PR** → **VRN10 PR**

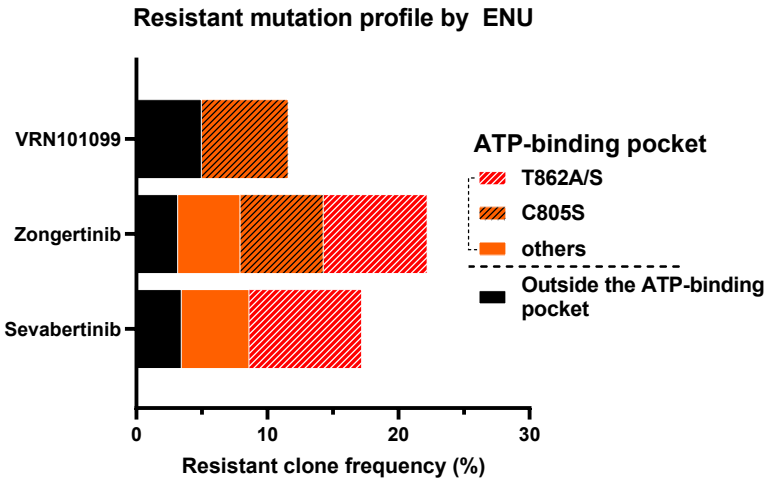


- 2 Lung TL PR achieved at first tumor assessment of -56.1%
- Deep partial response following relapse on sevabertinib, ELVN-002, and T-DXd
- **Brain NTL also decreased**

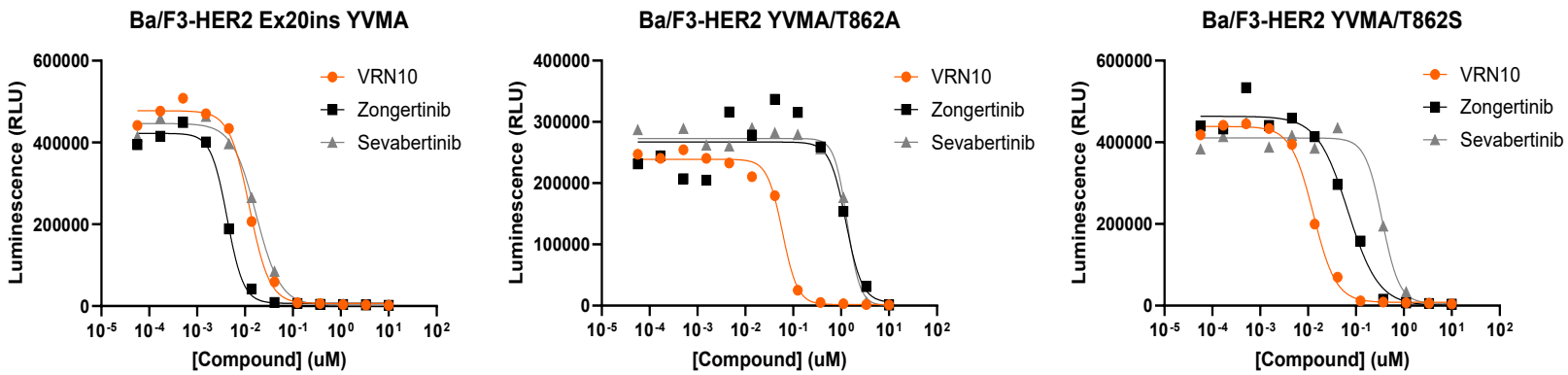
Evaluation of resistance in ENU-induced mutants

(A)ENU-induced drug-resistant mutation profiles.
(B)GI50 values in YVMA and YVMA with secondary mutations (YVMA+mutation) (n = 3)
(C)Fold changes of GI50 shifts in YVMA mutation models.

A



B



C

	ENU-induced mutation / YVMA GI_{50} shifting	
	T862S	T862A¶
VRN10	1.0	4.8
Zongertinib	16.1	299
Sevabertinib	19.8	78.4

¶: HER2 T862A also confers cross-resistance to competing agents like zongertinib and sevabertinib (Yuji Shibata et al., 2026 AACR).

Creating Novel Therapeutics
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Thank You