1차 치료 / Combi

KEYNOTE 407

KR-KEY-00390 12/2022

Selected Safety Information (SSI)

MSD's promotional materials are mandated to present Selected Safety Information aiming for balanced delivery of product advantages and limitations.

Here you can find **the latest version of KEYTRUDA's Selected Safety Information.**

Please read before entering.

SSI 바로가기

KR-KEY-00229

Final Analysis of KEYNOTE-407 Study design

PD-L1 발현율에 관계없이 전이성 편평 비소세포폐암의 1차 치료로서 키트루다 병용요법에 대한 연구[1]

KEYNOTE-407

전이성 편평 비소세포폐암에 대한 무작위, 이중눈가림, 다기관, 위약 대조, 3상 임상연구[a]

▶ **The primary endpoint :** 전체 생존기간(OS), 무진행 생존기간(PFS) ▶ **Secondary endpoint :** 객관적 반응률(ORR), 반응기간(DOR), 안전성(Safety)

전이성 편평 비소세포폐암 환자[b] (n=559)

- 18세 이상
- 측정가능한 질병 (RECIST ver 1.1)
- 이전 전신 치료 경험이 없는 환자
- ECOG PS 0 또는 1

→ 1:1로 환자 무작위 배정

키트루다 병용요법 (n=278)

키트루다 200 mg + carboplatin AUC 6 mg/mL/min + paclitaxel 200 mg/m^2 또는 nab-paclitaxel 100 mg/m^2 (QW)

(Q3W, 4회)

→ **키트루다** 200 mg (Q3W)

→ 총합 35회까지 투여 (질환이 진행되거나 허용 불가능한 독성이 발생하지 않은 경우)

Placebo 병용요법 (n=281)

Placebo + carboplatin AUC 6 mg/mL/min + paclitaxel 200 mg/m^2 또는 nab-paclitaxel 100 mg/m^2 (QW)

(Q3W, 4회)

→ Placebo (Q3W)

→ 총합 35회까지 투여 (질환이 진행된 경우 키트루다 단독요법으로 crossover 허용)

- **Stratification factors :**
  - PD-L1 발현비율 (TPS ≥1% vs. <1%)
  - Taxane (paclitaxel vs. nab-paclitaxel)
  - Geographic region (East Asia vs. non-East Asia)

- **기존 연구에서 추가된 사항 :**
  - 16개월 추가 follow-up
  - 후속 치료에 대한 1차 치료로서의 키트루다 병용요법의 임상적 이점 평가(PFS-2[c])
  - Simplified two-stage model을 이용한 crossover adjusted OS 분석

a. As of the data cutoff for this analysis (May 9, 2019), median (range) time from randomization to death or the date of data cutoff for those who were alive was 14.3 (0.1-31.3) months **b.** Intention-to-treat population **c.** Defined as the time from randomization to objective tumor progression on next-line treatment or death, whichever occurred first

PD-L1 : Programmed death ligand 1, **OS :** Overall survival, **PFS :** Progression free survival, **ORR :** Objective response rate, **DOR :** Duration of response, **RECIST :** Response Evaluation Criteria in Solid Tumors, **ECOG PS :** Eastern Cooperative Oncology Group performance status, **AUC :** Area under the curve, **QW :** Once weekly, **Q3W :** Once every 3 weeks, **TPS :** Tumor proportion score, **PFS-2 :** Progression-free survival in the next line

Reference & Study design

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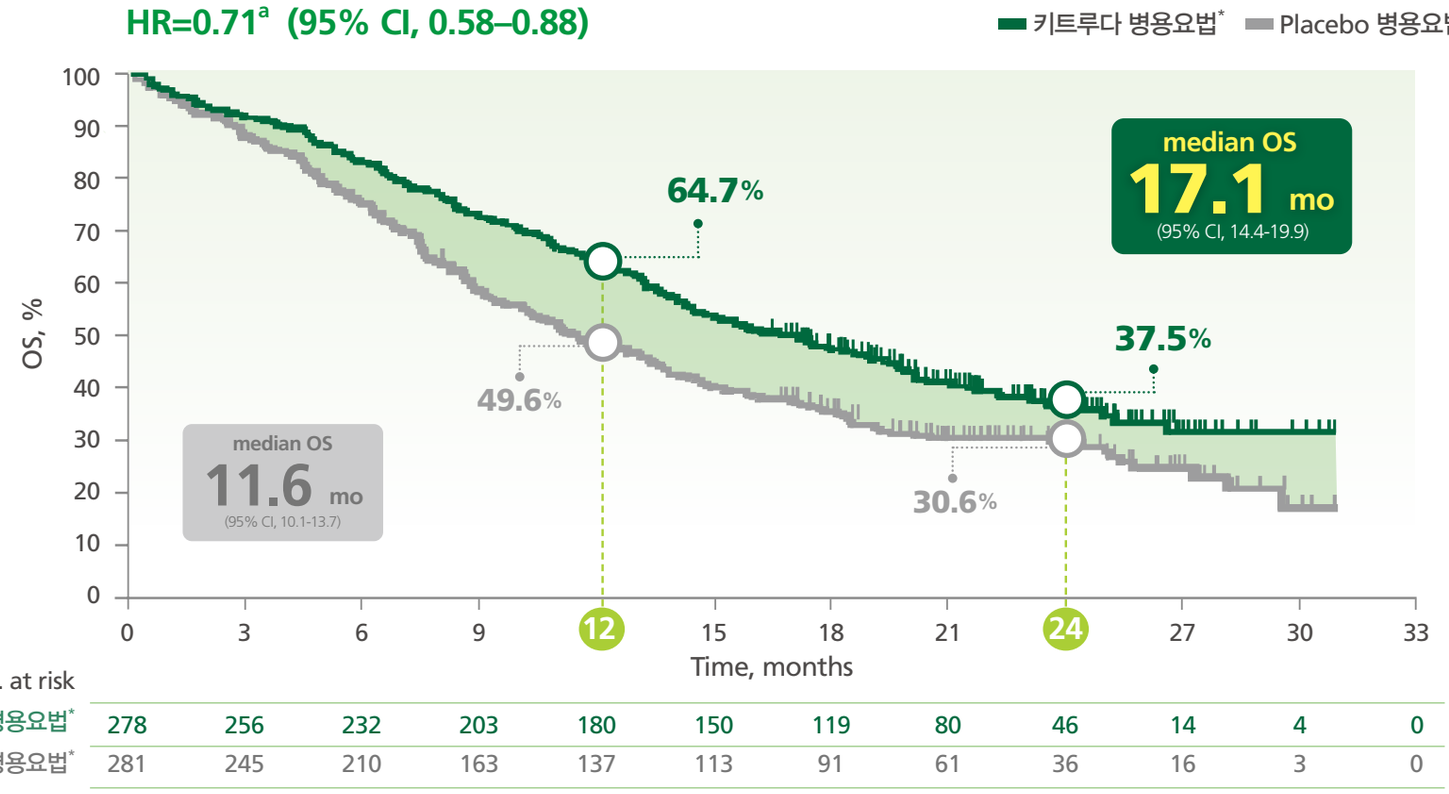
전체 생존기간 (OS) - Overall population

Kaplan-Meier Estimates of OS in KEYNOTE-407[1]

HR=0.71[a] (95% CI, 0.58–0.88)



No. at risk												
키트루다 병용요법*	278	256	232	203	180	150	119	80	46	14	4	0
Placebo 병용요법*	281	245	210	163	137	113	91	61	36	16	3	0

Adapted from Paz-Ares L, *et al.*[1]

- 전체 생존기간의 중앙값은 키트루다 병용요법* 투여군에서 17.1개월(95% CI, 14.4-19.9), Placebo 병용요법* 투여군에서 11.6개월(95% CI, 10.1-13.7) 이었습니다.
- Placebo 병용요법* 투여군 중 **114명의 환자(40.6%)**가 질병 진행 후 키트루다 단독요법으로 **crossover**하였습니다

키트루다 병용요법* 투여군은, Placebo 병용요법* 투여군 대비

사망 위험 29% 감소 & mOS 1.5배 연장

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)

a. Assessed with a stratified Cox proportional hazards model

OS : Overall survival, **HR :** Hazard ratio, **CI :** Confidence interval, **mOS :** median OS

Reference & Study design

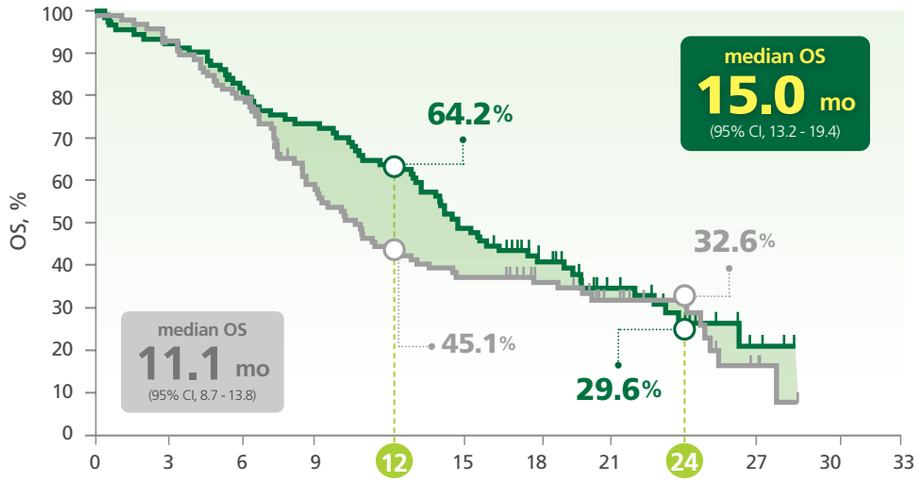
전체 생존기간 (OS) - According to PD-L1 TPS

Kaplan-Meier Estimates of OS in KEYNOTE-407[1]

키트루다 병용요법* Placebo 병용요법*

PD-L1 TPS <1%

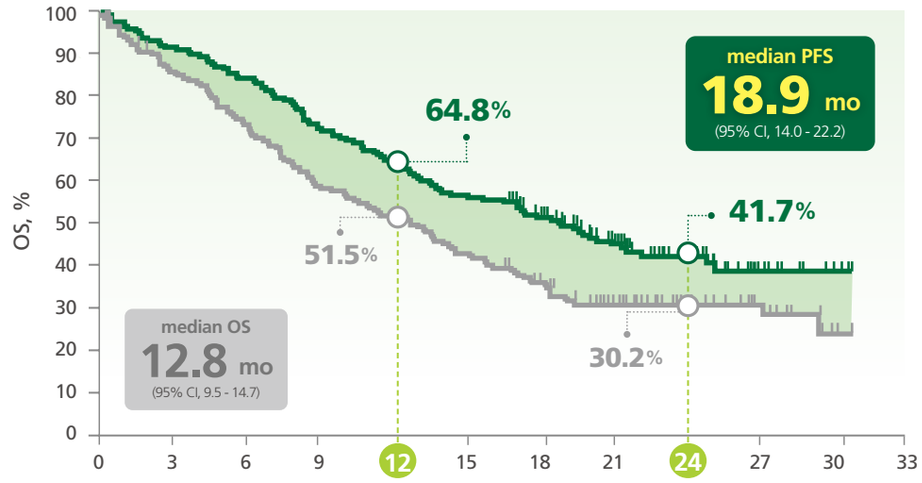
HR=0.79[a] (95% CI, 0.56-1.11)



No. at risk												
키트루다 병용요법*	95	88	78	70	61	47	34	21	13	3	0	0
Placebo 병용요법*	99	92	79	58	44	37	31	19	13	4	0	0

PD-L1 TPS ≥1%

HR=0.67[a] (95% CI, 0.51-0.87)



No. at risk												
키트루다 병용요법*	176	161	148	127	114	99	82	57	32	11	4	0
Placebo 병용요법*	177	150	128	102	90	74	58	40	23	12	3	0

Adapted from Paz-Ares L, *et al.*[1]

키트루다 병용요법* 투여군은, Placebo 병용요법* 투여군 대비

PD-L1 발현율에 관계없이 사망 위험 감소 및 mOS 연장

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)

a. Assessed with a stratified Cox proportional hazards model

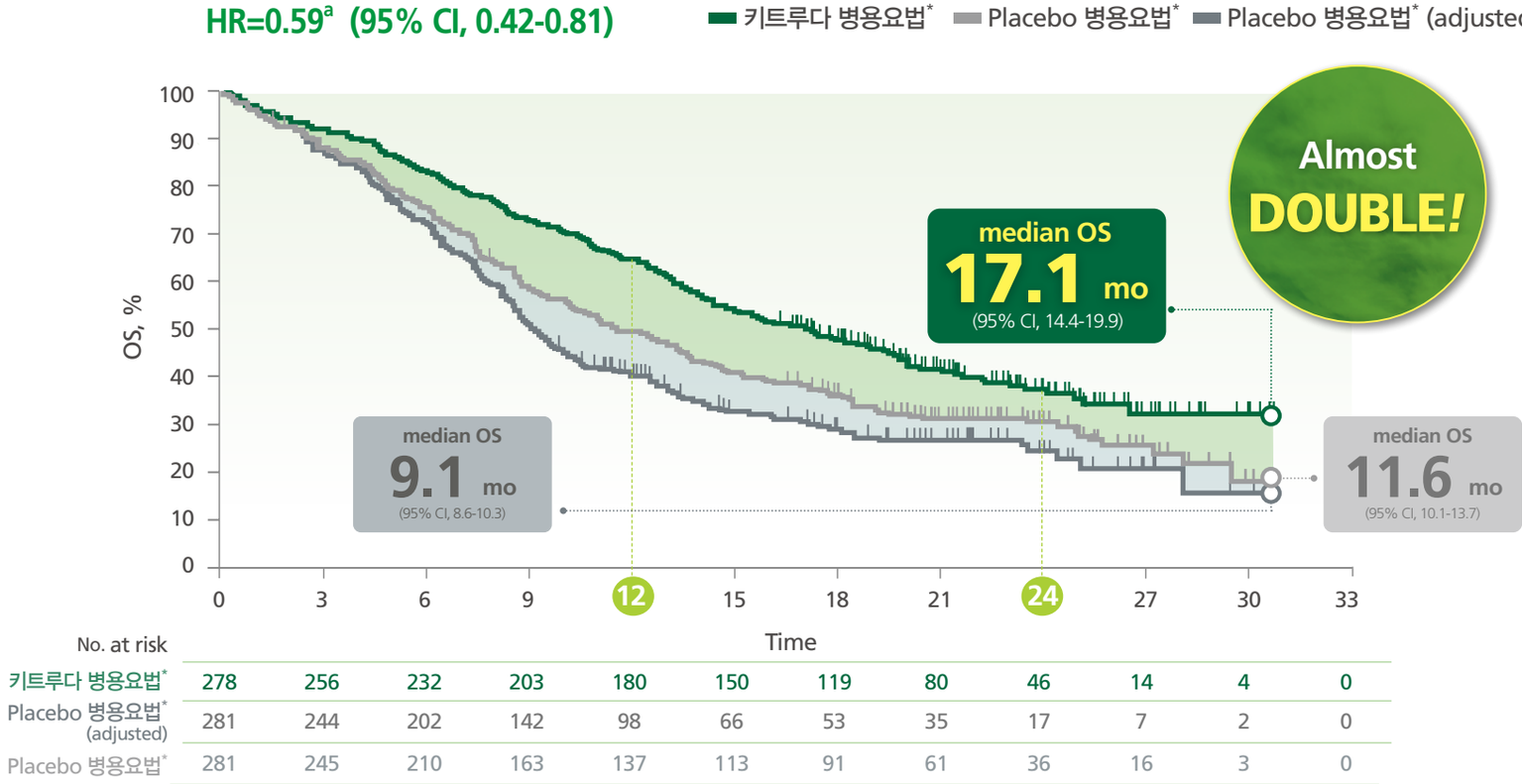
OS : Overall survival, **HR :** Hazard ratio, **CI :** Confidence interval, **mo :** Month, **mOS :** median OS, **PD-L1 :** Programmed death ligand 1, **TPS :** Tumor proportion score

Reference & Study design

Crossover adjusted OS - Overall population

Crossover-adjusted OS in KEYNOTE-407[1]

HR=0.59[a] (95% CI, 0.42-0.81)



No. at risk												
키트루다 병용요법*	278	256	232	203	180	150	119	80	46	14	4	0
Placebo 병용요법* (adjusted)	281	244	202	142	98	66	53	35	17	7	2	0
Placebo 병용요법*	281	245	210	163	137	113	91	61	36	16	3	0

Adapted from Paz-Ares L, *et al.*[1]

- On-study crossover에 따른 영향을 평가하고 bias를 조정하기 위해, simplified two-stage model을 이용한 OS에 대한 추가 분석이 수행되었습니다.
- Placebo 병용요법* 투여군에서 114명(40.6%)의 환자가 키트루다로 crossover 하였습니다.[b]

Crossover-adjustment 결과, **키트루다 병용요법* 투여군**은 Placebo 병용요법* 투여군 대비

사망 위험 41% 감소 & mOS 약 2배 연장

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)

a. Assessed with a stratified Cox proportional hazards model **b.** 73 patients in the placebo plus chemotherapy group experienced disease progression per RECIST version 1.1, but did not receive on-study crossover

OS : Overall survival, **HR :** Hazard ratio, **CI :** Confidence interval, **mOS :** median OS

Reference & Study design

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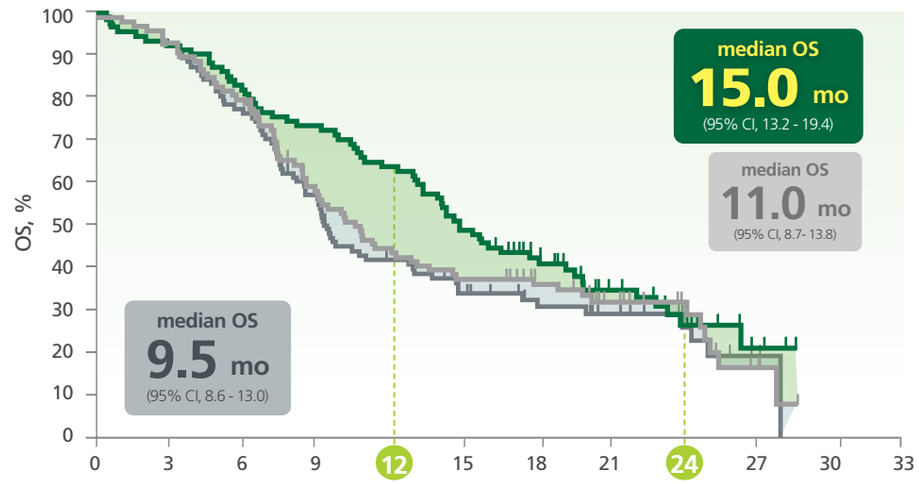
Crossover adjusted OS - According to PD-L1 TPS

Crossover-adjusted OS in KEYNOTE-407[1]

키트루다 병용요법* Placebo 병용요법* Placebo 병용요법* (adjusted)

PD-L1 TPS <1%

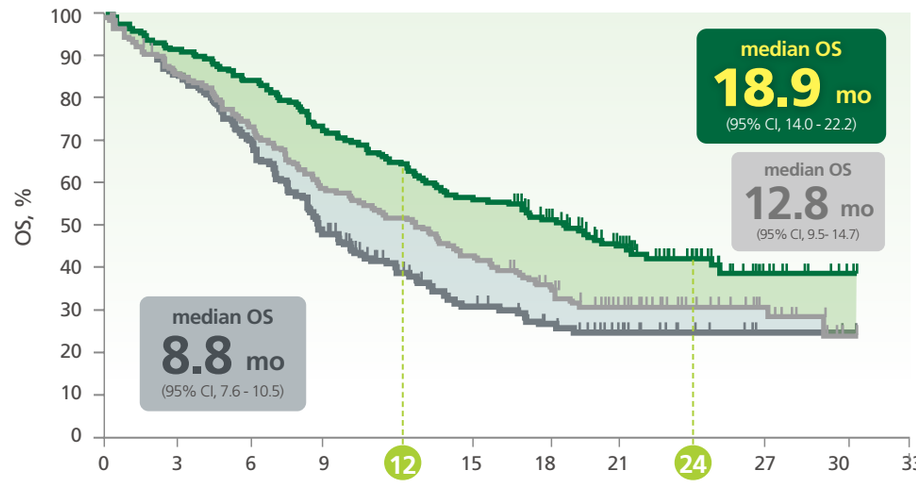
HR=0.70[a] (95% CI, 0.42-1.17)



No. at risk												
키트루다 병용요법*	95	88	78	70	61	47	34	21	13	3	0	0
Placebo 병용요법* (adjusted)	99	92	77	56	40	27	21	15	10	3	0	0
Placebo 병용요법*	99	92	79	58	44	37	31	19	13	4	0	0

PD-L1 TPS ≥1%

HR=0.52[a] (95% CI, 0.34-0.80)



No. at risk												
키트루다 병용요법*	176	161	148	127	114	99	82	57	32	11	4	0
Placebo 병용요법* (adjusted)	177	149	122	82	52	38	29	18	8	3	2	0
Placebo 병용요법*	177	150	128	102	90	74	58	40	23	12	3	0

Adapted from Paz-Ares L, *et al*.[1]

Crossover-adjustment 결과, **키트루다 병용요법* 투여군**은 Placebo 병용요법* 투여군 대비

PD-L1 발현율에 관계없이 사망 위험 감소 및 mOS 연장

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)

a. Assessed with a stratified Cox proportional hazards model

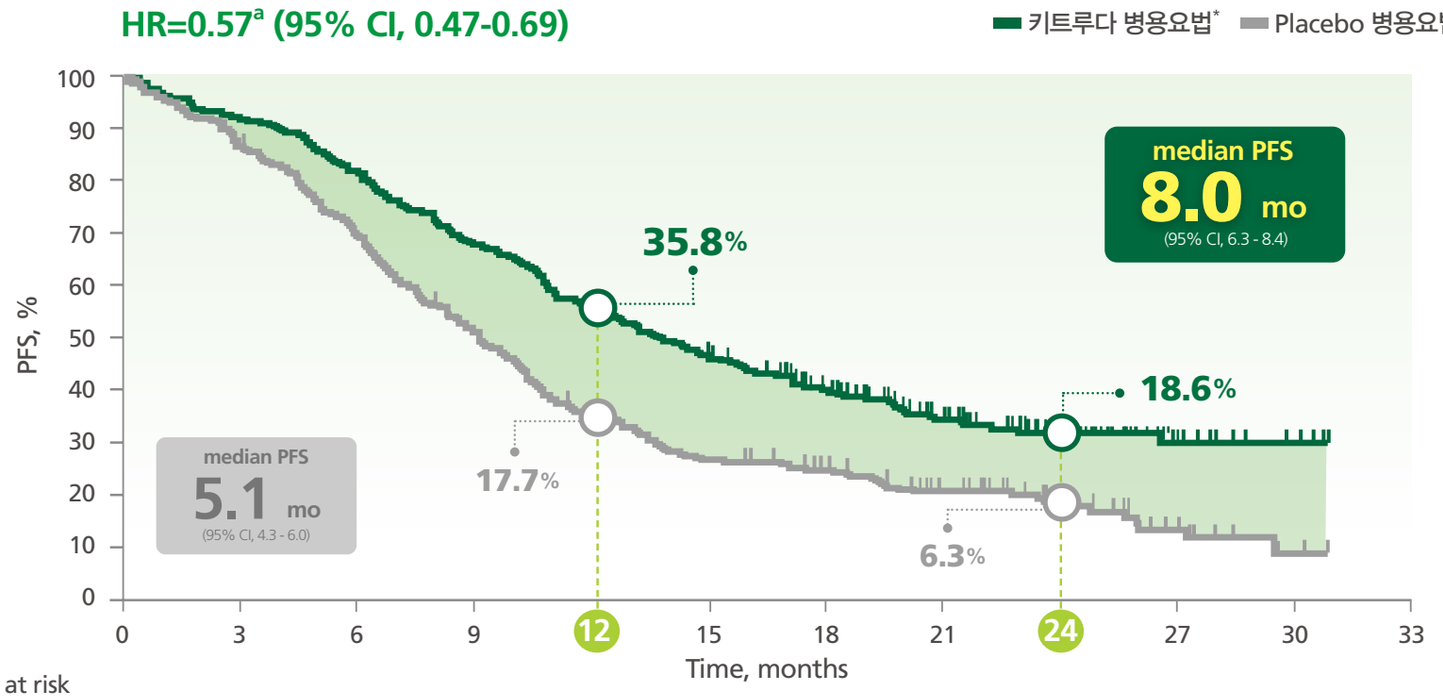
OS : Overall survival, **HR :** Hazard ratio, **CI :** Confidence interval, **mo :** Month, **mOS :** median OS, **PD-L1 :** Programmed death ligand 1, **TPS :** Tumor proportion score

Reference & Study design

무진행 생존기간 (PFS) - Overall population

Kaplan-Meier Estimates of PFS in KEYNOTE-407[1]

HR=0.57[a] (95% CI, 0.47-0.69)



No. at risk												
키트루다 병용요법*	278	235	179	113	96	75	59	45	25	5	0	0
Placebo 병용요법*	281	204	122	61	46	33	26	17	7	1	0	0

Adapted from Paz-Ares L, *et al*.[1]

- 무진행 생존기간 중앙값은 키트루다 병용요법* 투여군에서 8.0개월(95% CI, 6.3-8.4), Placebo 병용요법* 투여군에서 5.1개월 (95% CI, 4.3-6.0) 이었습니다.

키트루다 병용요법* 투여군은, Placebo 병용요법* 투여군 대비

질병 진행 또는 사망 위험 43% 감소 & mPFS 약 1.6배 연장

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)

a. Assessed with a stratified Cox proportional hazards model

PFS : Progression free survival, **HR :** Hazard ratio, **CI :** Confidence interval, **mPFS :** median PFS

Reference & Study design

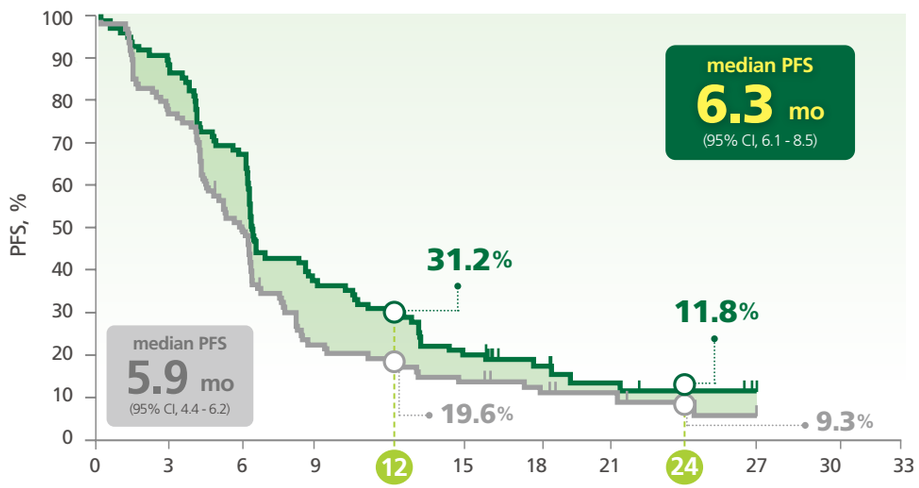
무진행 생존기간 (PFS) - According to PD-L1 TPS

Kaplan-Meier Estimates of PFS in KEYNOTE-407[1]

키트루다 병용요법* Placebo 병용요법*

PD-L1 TPS <1%

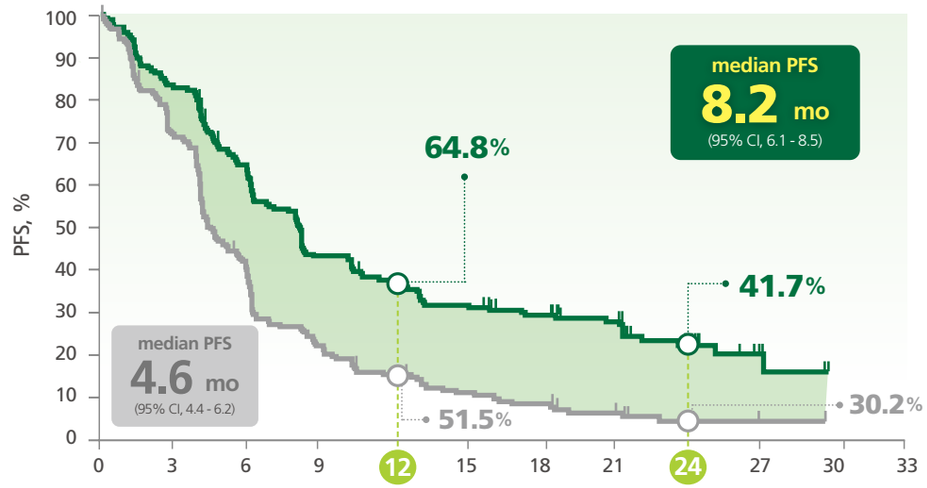
HR=0.67[a] (95% CI, 0.49-0.91)



No. at risk												
키트루다 병용요법*	95	82	64	35	29	19	11	7	5	0	0	0
Placebo 병용요법*	99	76	48	21	18	13	10	6	3	0	0	0

PD-L1 TPS ≥1%

HR=0.50[a] (95% CI, 0.39-0.63)



No. at risk												
키트루다 병용요법*	176	161	148	127	114	99	82	57	32	11	4	0
Placebo 병용요법*	177	150	128	102	90	74	58	40	23	12	3	0

Adapted from Paz-Ares L, *et al.*[1]

키트루다 병용요법* 투여군은 Placebo 병용요법* 투여군 대비

PD-L1 발현율에 관계없이 질병 진행 또는 사망 위험 감소 & mPFS 연장

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)

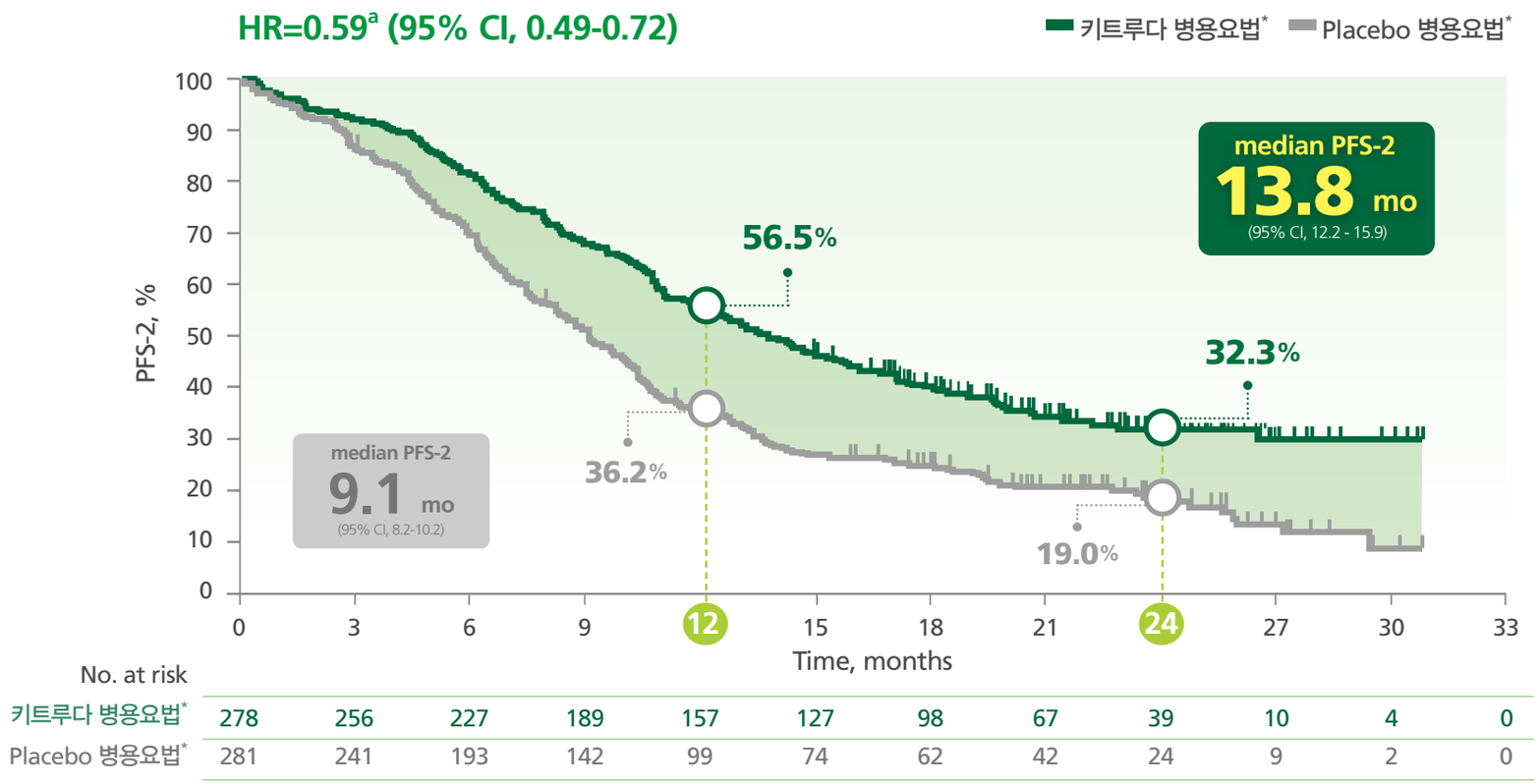
a. Assessed with a stratified Cox proportional hazards model

PFS : Progression free survival, **HR :** Hazard ratio, **CI :** Confidence interval, **mo :** Month, **mPFS :** median PFS, **PD-L1 :** Programmed death ligand 1, **TPS :** Tumor proportion score

Reference & Study design

무진행 생존기간-2 (PFS-2) - Overall population

Kaplan-Meier Estimates of PFS-2 in KEYNOTE-407[1]



No. at risk												
키트루다 병용요법*	278	256	227	189	157	127	98	67	39	10	4	0
Placebo 병용요법*	281	241	193	142	99	74	62	42	24	9	2	0

Adapted from Paz-Ares L, *et al.*[1]

- PFS-2 중앙값은 키트루다 병용요법* 투여군에서 13.8개월(95% CI, 12.2-15.9), Placebo 병용요법* 투여군에서 9.1개월 (95% CI, 8.2-10.2) 이었습니다.
- **1차부터 키트루다 병용요법*으로 시작**하는 것은 **다음 차수의 치료 효과**에도 **긍정적 영향**을 줍니다.

키트루다 병용요법* 투여군은, Placebo 병용요법* 투여군 대비

다음 차수 치료 중 질병 진행 또는 사망 위험 41% 감소 & mPFS-2 약 1.5배 연장

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)

a. Assessed with a stratified Cox proportional hazards model

PFS-2 : Progression-free survival in the next line, **HR :** Hazard ratio, **CI :** Confidence interval, **mPFS-2 :** median PFS-2

Reference & Study design

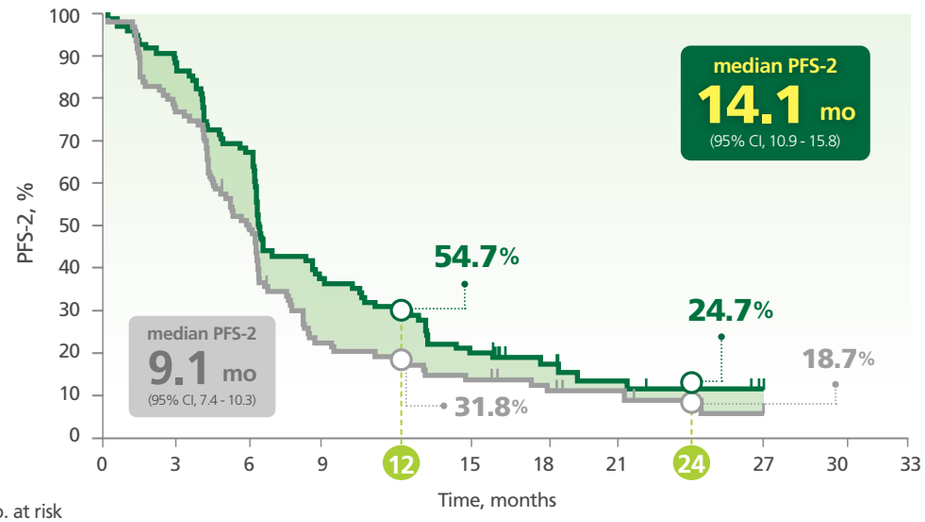
무진행 생존기간-2 (PFS-2) - According to PD-L1 TPS

Kaplan-Meier estimates of PFS-2 in KEYNOTE-407[1]

키트루다 병용요법* Placebo 병용요법*

PD-L1 TPS <1%

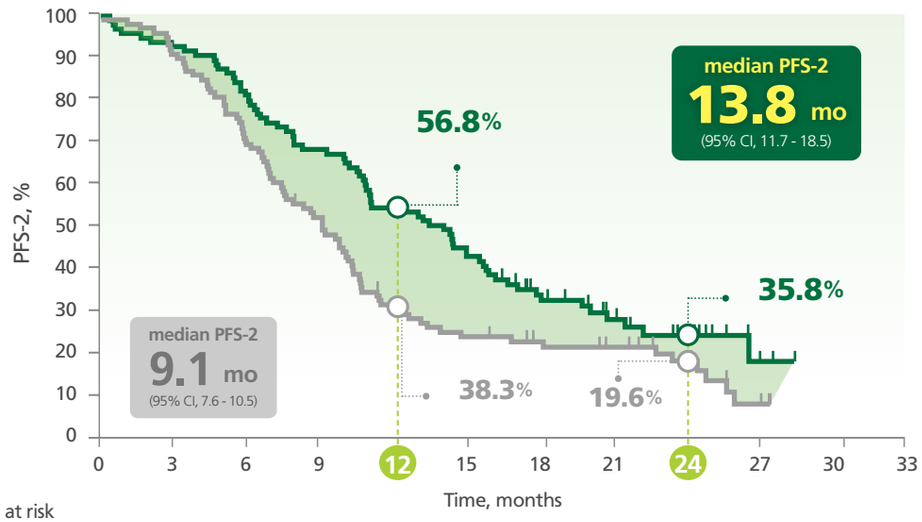
HR=0.61[a] (95% CI, 0.44-0.85)



No. at risk												
키트루다 병용요법*	95	88	77	65	52	40	27	17	11	2	0	0
Placebo 병용요법*	99	90	69	51	30	23	19	16	9	2	0	0

PD-L1 TPS ≥1%

HR=0.58[a] (95% CI, 0.45-0.75)



No. at risk												
키트루다 병용요법*	176	161	144	118	100	84	68	48	27	8	4	0
Placebo 병용요법*	177	148	121	89	67	49	41	24	15	7	2	0

Adapted from Paz-Ares L, *et al.*[1]

키트루다 병용요법* 투여군은, Placebo 병용요법* 투여군 대비

PD-L1 발현율에 관계없이 다음 차수 치료 중 질병 진행 또는 사망 위험 감소 & mPFS-2 연장

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)

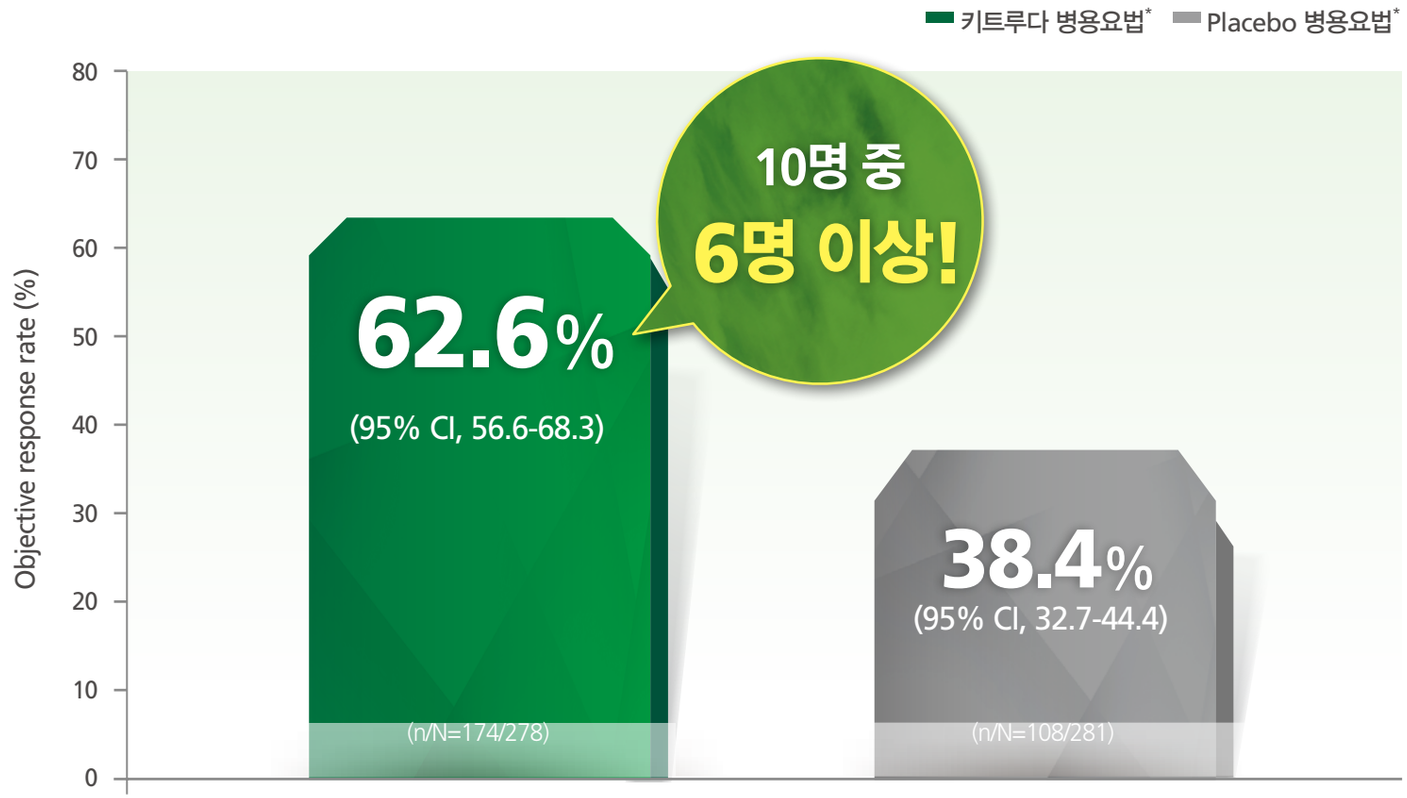
a. Assessed with a stratified Cox proportional hazards model

PFS-2 : Progression-free survival in the next line, **HR :** Hazard ratio, **CI :** Confidence interval, **mo :** Month, **PD-L1 :** Programmed death ligand 1, **TPS :** Tumor proportion score, **mPFS-2 :** median PFS-2

Reference & Study design

객관적 반응률 (ORR) - Overall population

ORR from KEYNOTE-407[1]



- 객관적 반응률은 키트루다 병용요법* 투여군에서 62.6%(95% CI, 56.6-68.3), Placebo 병용요법* 투여군에서 38.4% (95% CI, 32.7-44.4) 이었습니다.
- 반응 지속기간의 중앙값은 키트루다 병용요법* 투여군에서 8.8개월 (Range, 1.3+ to 28.4+), Placebo 병용요법* 투여군에서 4.9개월(Range, 1.3+ to 28.3+) 이었습니다.[a]

키트루다 병용요법* 투여군은 **10명 중 6명 이상이 반응**

(Placebo 병용요법* 투여군 대비 **약 1.6배의 ORR**)

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)

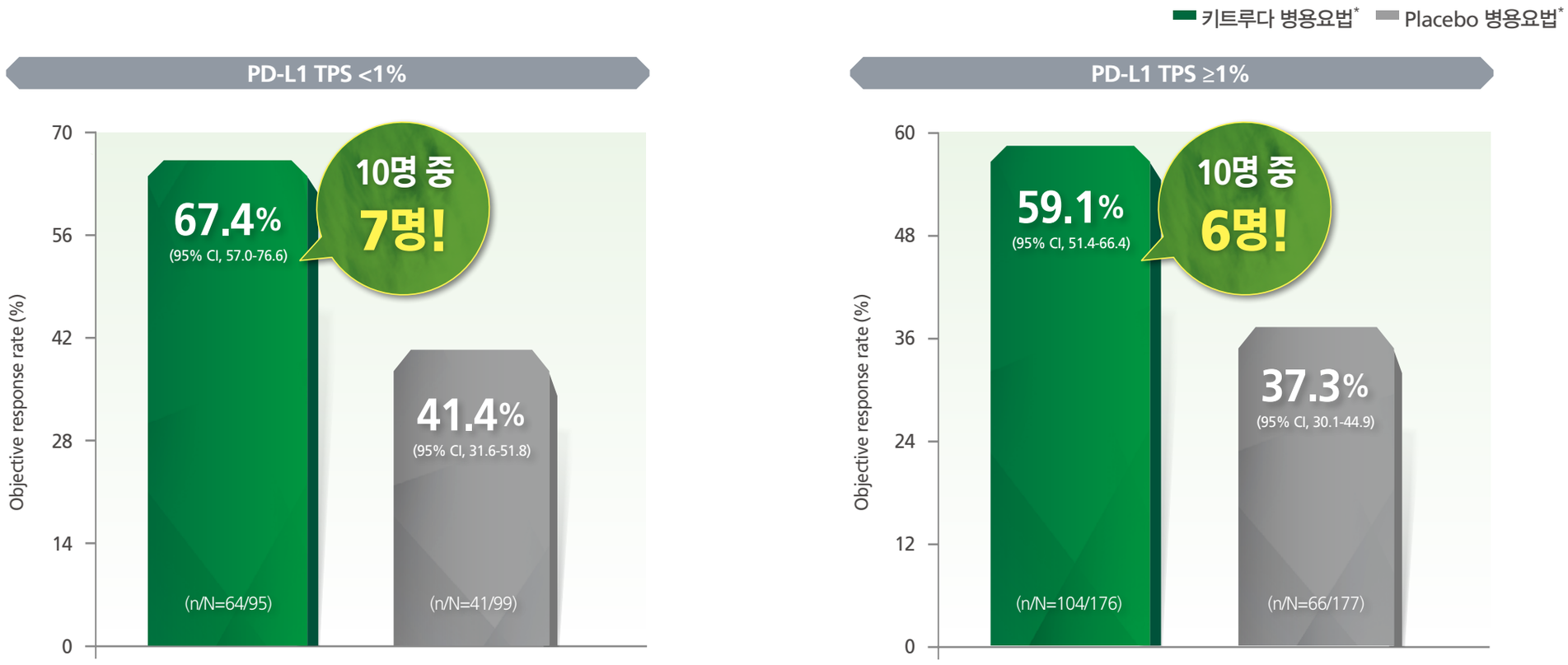
a. "+" indicates there was no progressive disease as of last assessment before the data cutoff date

ORR : Objective response rate, **CI :** Confidence interval

Reference & Study design

객관적 반응률 (ORR) - According to PD-L1 TPS

ORR from KEYNOTE-407[1]



키트루다 병용요법* 투여군은, Placebo 병용요법* 투여군 대비

PD-L1 발현율에 관계없이 ORR 증가 (약 1.6배)

[Median DOR(months)] TPS <1%: 6.9(range; 1.4+ to 25.4+) vs. 5.7(range; 1.4+ to 25.6+), TPS ≥1%: 10.4(range; 1.3+ to 28.4+) vs. 4.7(range; 1.3+ to 28.3+), in the KEYTRUDA combination group and placebo combination group, respectively ("+" indicates there was no progressive disease as of last assessment before the data cutoff date)

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)

ORR : Objective response rate, **CI :** Confidence interval, **PD-L1 :** Programmed death ligand 1, **TPS :** Tumor proportion score

Reference & Study design

안전성 프로파일

Incidence of All-Cause AEs, Immune-Mediated AEs, and Infusion Reactions, Safety Population[1]

Event	키트루다 병용요법* (N = 278)	Placebo 병용요법* (N = 280)
	number of patients (%)	
1회 이상 발생한 이상반응	274 (98.6)	275 (98.2)
3등급 이상	206 (74.1)	195 (69.6)
치료 중단으로 이어진 이상반응		
1개 이상의 치료 중단	76 (27.3)	37 (13.2)
모든 치료 중단[a]	45 (16.2)	20 (7.1)
5등급	31 (11.2)	19 (6.8)
사망으로 이어진 치료관련 이상반응	12 (4.3)	5 (1.8)
면역-매개 이상반응 및 주입 관련 반응	98 (35.3)	25 (8.9)
3등급 이상	37 (13.3)	9 (3.2)

- 키트루다 병용요법* 투여군에서 가장 흔한 이상반응은 빈혈(54.7%), 탈모증(46.0%), 호중구 감소증(37.8%), 오심(36.0%) 등이었습니다.
- 키트루다 병용요법* 투여군의 가장 흔한 면역-매개 이상반응 및 주입 관련 이상반응은 갑상선 저하증(12.2%), 갑상선기능항진증(6.8%), 폐렴(8.3%) 등이었습니다.

키트루다 병용요법* 투여군은
전반적으로 **양호한 내약성**을 보임

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)

a. Includes patients who discontinued pembrolizumab or placebo, carboplatin, and taxane owing to an AE at any time and patients who discontinued pembrolizumab or placebo owing to an AE after completing four 3-week cycles of carboplatin and taxane.

AE : Adverse event

Reference & Study design

Final Analysis of KEYNOTE-407 Summary

PD-L1 발현율에 관계없이 전이성 편평 비소세포폐암의 1차 치료로서 키트루다 병용요법* 연구[1]

Crossover-adjusted
전체 생존기간 중앙값(mOS) 연장

Almost DOUBLE!
(vs. Placebo 병용요법* 투여군)

객관적 반응률(ORR) 증가

10명 중 6명 이상

PD-L1 발현이 음성이거나, **PD-L1 검사결과가 없는 환자**를 포함한 **모든 squamous mNSCLC 환자**에게

"키트루다 1차 병용요법*으로 More TOMORROWs의 가능성을 열어주세요!"

* Carboplatin AUC 6 mg/mL/min (Q3W) + Paclitaxel 200 mg/m^2 (Q3W) or nab-paclitaxel 100 mg/m^2 (QW)
PD-L1 : Programmed death ligand 1, **mOS :** median OS, **ORR :** Objective response rate, **mNSCLC :** metastatic non-small cell lung cancer

Reference & Study design

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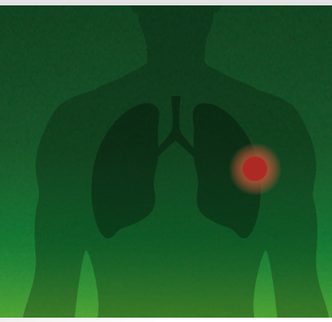
KEYNOTE-407 용법·용량

키트루다®와 Carboplatin 및 Paclitaxel(혹은 Nab-paclitaxel)과의 병용요법



치료 용량[1,2,a-d]

KEYTRUDA®
200 mg IV over 30 minutes (매 3주마다)

C — Carboplatin
AUC 6 mg/mL/min IV over 15-60 minutes (매 3주마다)

P — Paclitaxel with pre-medications
200 mg/m^2 IV over 3 hours (매 3주마다)

or

nab-P — Nab-paclitaxel without pre-medications
100 mg/m^2 IV over 30 minutes
(매 3주 주기의 제 1일, 8일, 15일)

※ 이 약을 화학요법제와 병용하여 투여하는 경우 이 약이 먼저 투여되어야 합니다. 병용하여 투여하는 화학요법제의 허가사항을 함께 참고합니다.
1. 초기 4 cycles은 KEYTRUDA + Carboplatin + Paclitaxel 요법으로 투여합니다.
2. 이후엔 KEYTRUDA 단독 유지 요법으로 투여하며, 초기 4 cycles를 포함하여 총 35 cycles까지 투여 가능합니다.

전처치 용법·용량[3,4,*]

D/D — Dexamethasone(or equivalent)
20 mg PO (Paclitaxel 투여 12시간과 6시간 전)

D — Diphenhydramine(or equivalent)
50 mg IV (Paclitaxel 투여 30-60분 전)

C — Cimetidine
300 mg IV (Paclitaxel 투여 30-60분 전)

or

R — Ranitidine
50 mg IV (Paclitaxel 투여 30-60분 전)

* All subjects should be pre-medicated with oral or intravenous steroid and anti-histamines according to the approved product label and/or standard practice. Additional pre-medications should be administered as per standard practice.

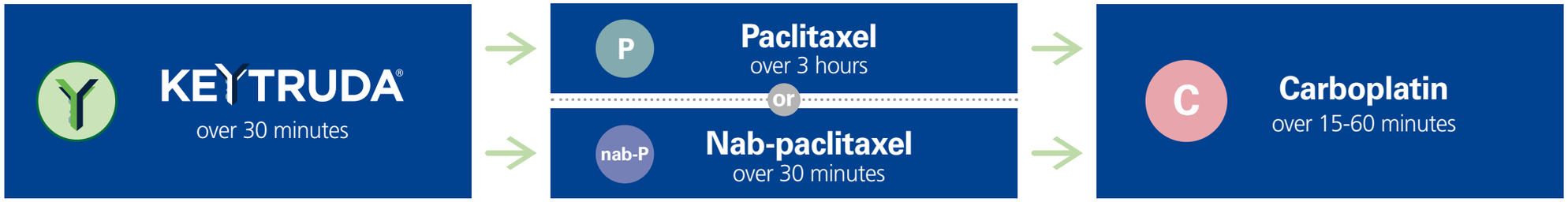
a. KEYTRUDA + carboplatin or and paclitaxel or nab-paclitaxel Q3W for 4 cycles **b.** KEYTRUDA was given Q3W for up to a total of 35 cycles **c.** Patients in placebo combination group who had disease progression verified by BICR were eligible to cross over. **d.** Treatment with KEYTRUDA continued until disease progression, unacceptable toxicity, or up to a total of 35 cycles.
AUC : area under the curve, **IV :** intravenous, **PO :** by mouth

Reference

KR-KEY-00390 12/2022

KEYNOTE-407 투여 스케줄

투여 스케줄[2-4]



* 기관마다 infusion pump의 다양성을 고려하여 30분 투여 시간에서 -5 mins ~ +10 mins window는 허용되었습니다.

	day 1	day 2	day 3	day 4	day 5	day 6	day 7
Cycle 1~4	KEYTRUDA® P or nab-P C D/D D C or R Paclitaxel only requires pre-medications						
	day 8 nab-P	day 9	day 10	day 11	day 12	day 13	day 14
	day 15 nab-P	day 16	day 17	day 18	day 19	day 20	day 21

a. Treatment with KEYTRUDA continued until disease progression, unacceptable toxicity, or up to a total of 35 cycles.
D/D : dexamethasone, **D :** diphenhydramine, **C :** cimetidine, **R :** ranitidine

Reference

KEYNOTE-407 투여 스케줄

투여 스케줄[2-4]

Cycle 1~4

day 1	day 2	day 3	day 4	day 5	day 6	day 7
KEYTRUDA + P or nab-P + C D/D D C or R	Paclitaxel only requires pre-medications					
day 8	**day 9**	**day 10**	**day 11**	**day 12**	**day 13**	**day 14**
nab-P						
day 15	**day 16**	**day 17**	**day 18**	**day 19**	**day 20**	**day 21**
nab-P						

Maintenance therapy

day 1	day 2	day 3	day 4	day 5	day 6	21 -day cycle continues
KEYTRUDA Maintenance therapy up to a total of 35 cycles[a]						

a. Treatment with KEYTRUDA continued until disease progression, unacceptable toxicity, or up to a total of 35 cycles.
D/D : dexamethasone, **D :** diphenhydramine, **C :** cimetidine, **R :** ranitidine

Reference

Reference

1. Paz-Ares L, *et al*. A Randomized, Placebo-Controlled Trial of Pembrolizumab Plus Chemotherapy in Patients With Metastatic Squamous NSCLC: Protocol-Specified Final Analysis of KEYNOTE-407. *J Thorac Oncol*. 2020 Oct;15(10):1657-1669.
2. Paz-Ares L, *et al*. A Randomized, Placebo-Controlled Trial of Pembrolizumab Plus Chemotherapy in Patients With Metastatic Squamous NSCLC: Protocol-Specified Final Analysis of KEYNOTE-407(protocol). *J Thorac Oncol.* 2020 Oct;15(10):1657-1669.
3. Paclitaxel 제품허가사항. 식품의약품안전처.
4. 대한폐암학회. 폐암진료지침 2011. Available at <https://www.lungca.or.kr/upload/LungCancer_Clinical_Practice_Guideline_2011.pdf> Accessed Nov. 03, 2020.

Study design

This study was conducted to evaluate the final efficacy and safety outcomes of KEYNOTE-407 study. A multicenter, randomized, double-blind, placebo-controlled, phase 3 KEYNOTE-407 trial was conducted to determine whether the addition of the PD-1 inhibitor (pembrolizumab) to platinum-based chemotherapy improves outcomes in patients with squamous NSCLC of any level of PD-L1 expression. Eligible patients were at least 18 years of age and had a histologically or cytologically confirmed diagnosis of stage IV squamous NSCLC. 559 patients were randomly assigned (1:1) to receive carboplatin (AUC 6 mg/mL/min Q3W) and either paclitaxel (200 mg/m^2 Q3W) or nab–paclitaxel (100 mg/m^2 Q1W), plus either 200 mg of pembrolizumab (n=278) or placebo (n=281) every 3 weeks for 4 cycles, followed by pembrolizumab or placebo for up to a total of 35 cycles. Randomization was stratified according to PD-L1 tumor proportion score (≥1% vs. <1%), choice of taxane (paclitaxel vs.nab-paclitaxel), and geographic region of enrollment (East Asia vs. the rest of the world). Crossover to pembrolizumab monotherapy was permitted among the patients in the placebo-combination group who had verified disease progression. The median duration of follow-up was 14.3 months. Primary end points were overall survival and progression-free survival.[1]

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