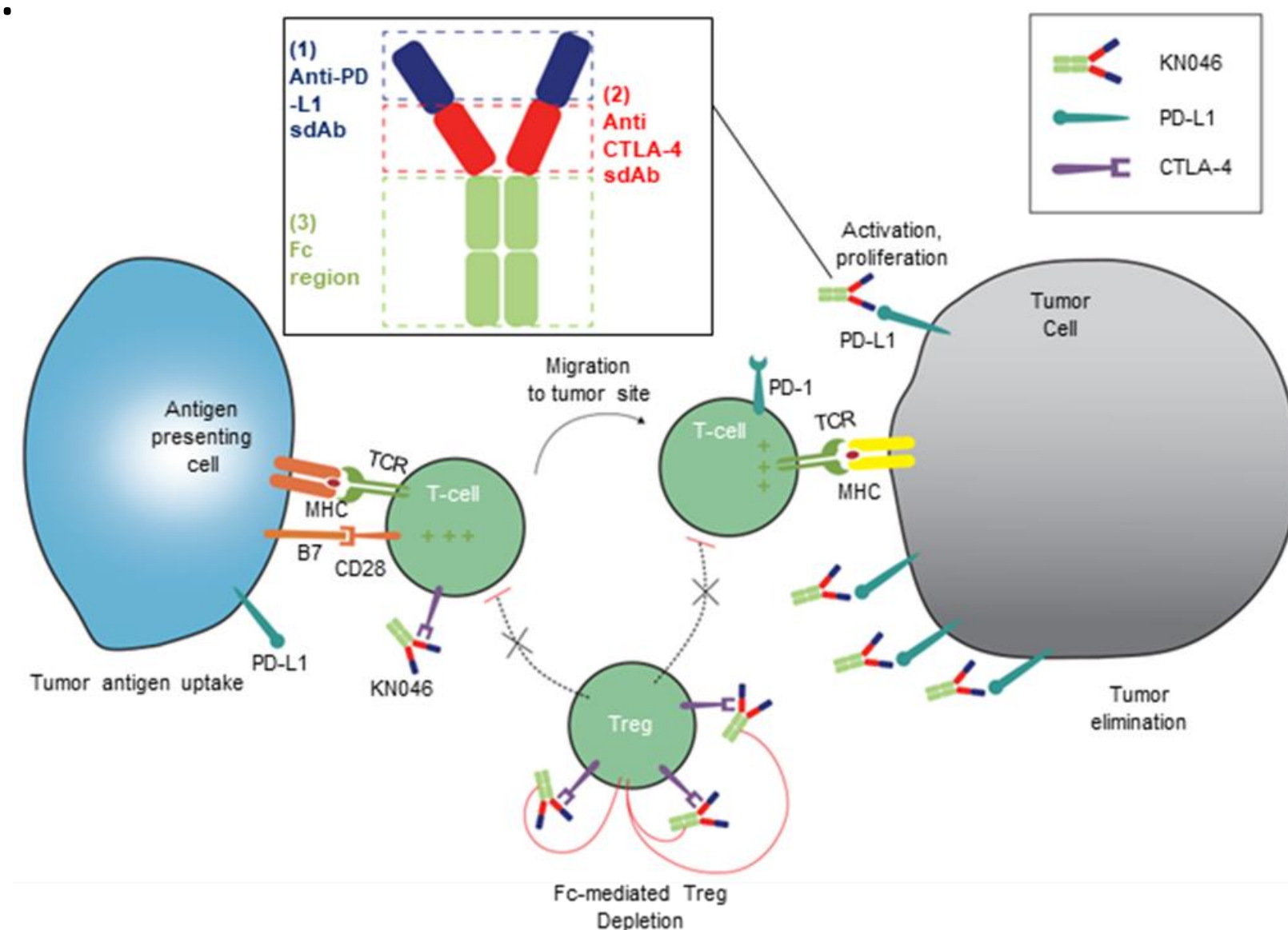


# Abstract # 9060: A Phase 2, Open-Label, Multi-Center Study to evaluate the efficacy, safety, and tolerability of KN046 in combination with chemotherapy in subjects with advanced non-small cell lung cancer

Authors: Yunpeng Yang, PhD, Sun Yat-sen University Cancer Center, Guangzhou, Guangdong, China

## Background:

- KN046 bifunctionally targets CTLA-4 and PD-L1.
- Limited peripheral distribution reduces treatment-associated on-target off-tumor toxicity.
- IgG1 Fc domain, CTLA-4 blocking-mediated Treg cells depletion.
- Study hypothesis: Due to dual PD-L1 and CTLA-4 inhibition, KN046 in combination with a standard of care chemo doublet can build more durable disease response and a higher OS benefit.



## Baseline characteristics:

Parameters	Total (N =87)
<b>Gender, n (%)</b>	
Male	66 (75.9%)
Female	21 (24.1%)
<b>Age (years)</b>	
Mean (SD)	59(9.13)
Median (Min, Max)	61.0 (32, 72)
<b>ECOG, n (%)</b>	
0	15 (17.2%)
1	72 (82.8%)
<b>Primary Tumor Type</b>	
Squamous Carcinoma	36 (41.3%)
Non-Squamous Carcinoma	51 (56.8%)
<b>Tumor PD-L1 expression</b>	
PD-L1 ≥1%	46 (55.4%)
PD-L1 <1%	37 (44.6%)

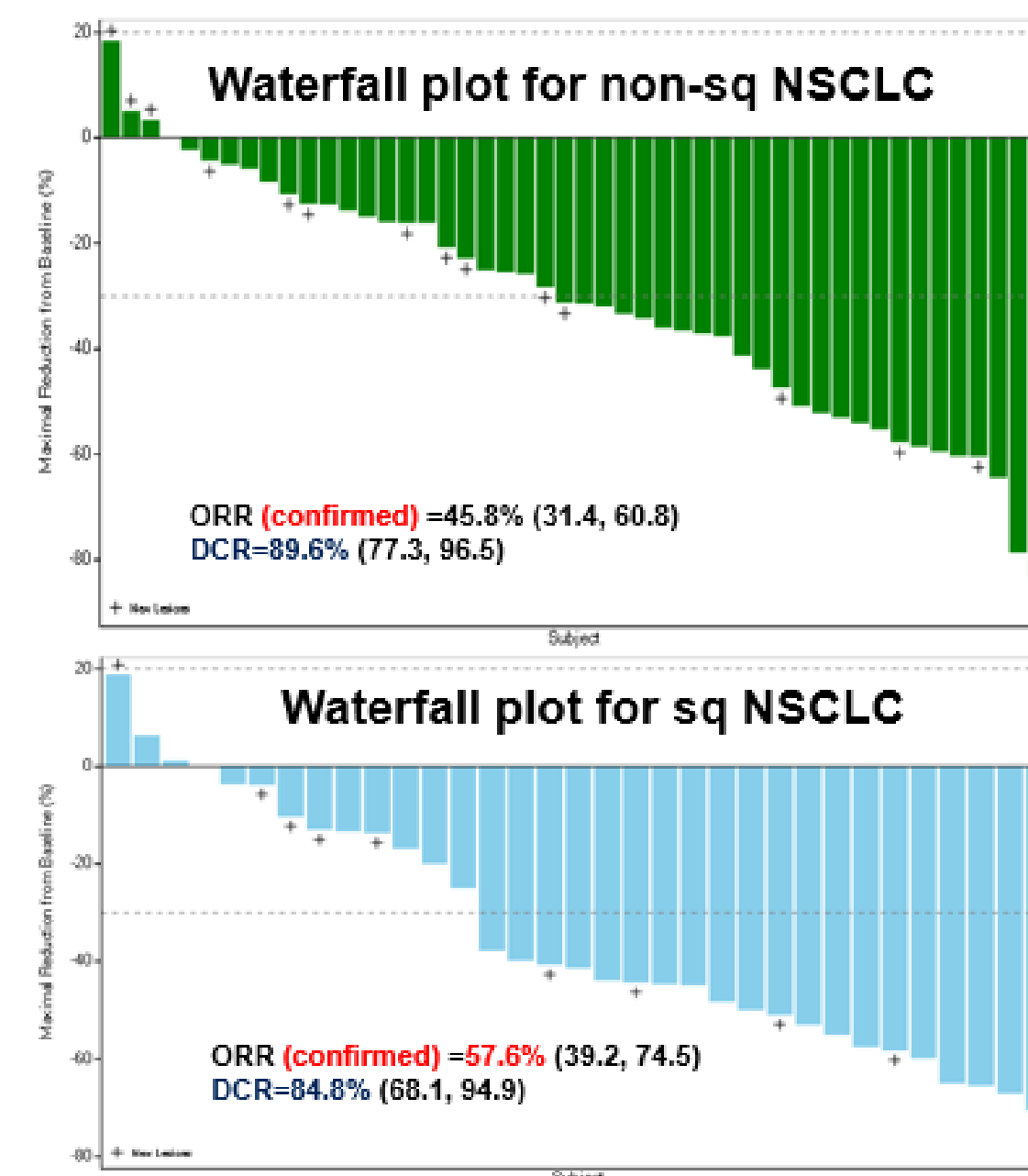
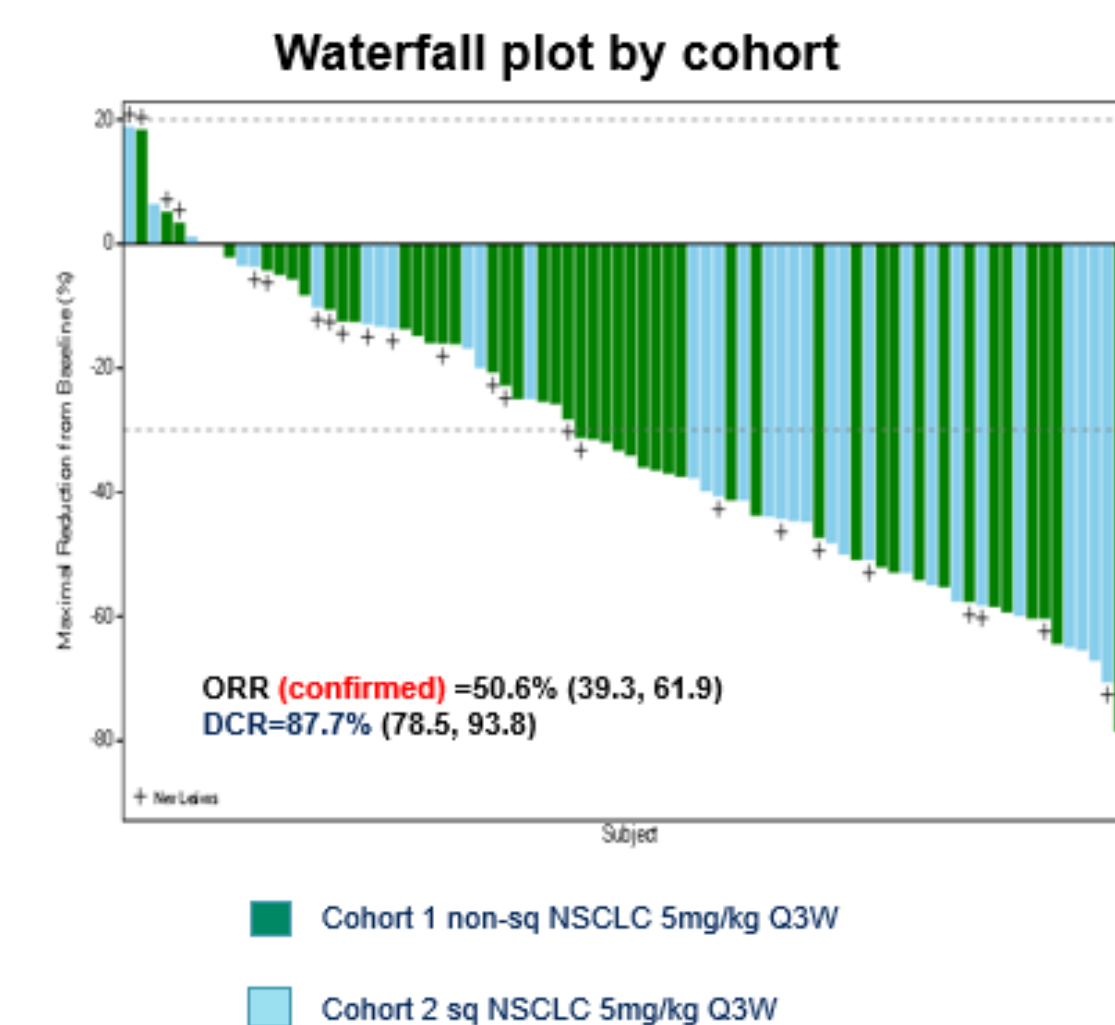
## TEAE (Grade ≥ 3):

Preferred Term (CTCAE v5.0)	Grade ≥ 3
<b>Subjects with at least 1 KN046 Related CTCAE Grade ≥ 3 TEAE</b>	<b>22(25.3%)</b>
Diarrhea	5 (5.7%)
Alanine aminotransferase increase	4 (4.6%)
Infusion related reaction	3 (3.4%)
Rash	3 (3.4%)
Aspartate aminotransferase increase	2 (2.3%)
Dermatitis allergic	2 (2.3%)
Immune-mediated pneumonitis	2 (2.3%)
Anaphylactoid reaction	1 (1.1%)
Autoimmune hepatitis	1 (1.1%)
Back pain	1 (1.1%)

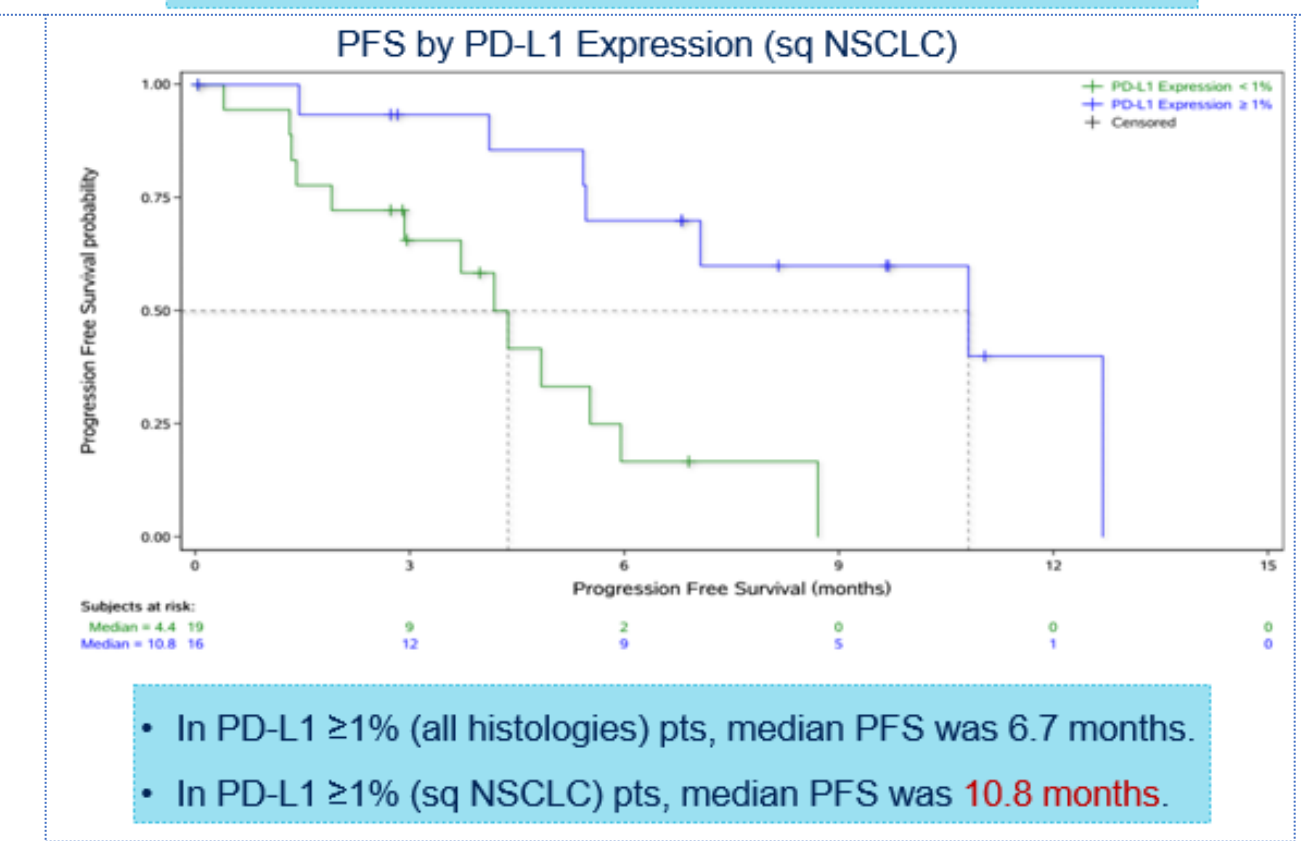
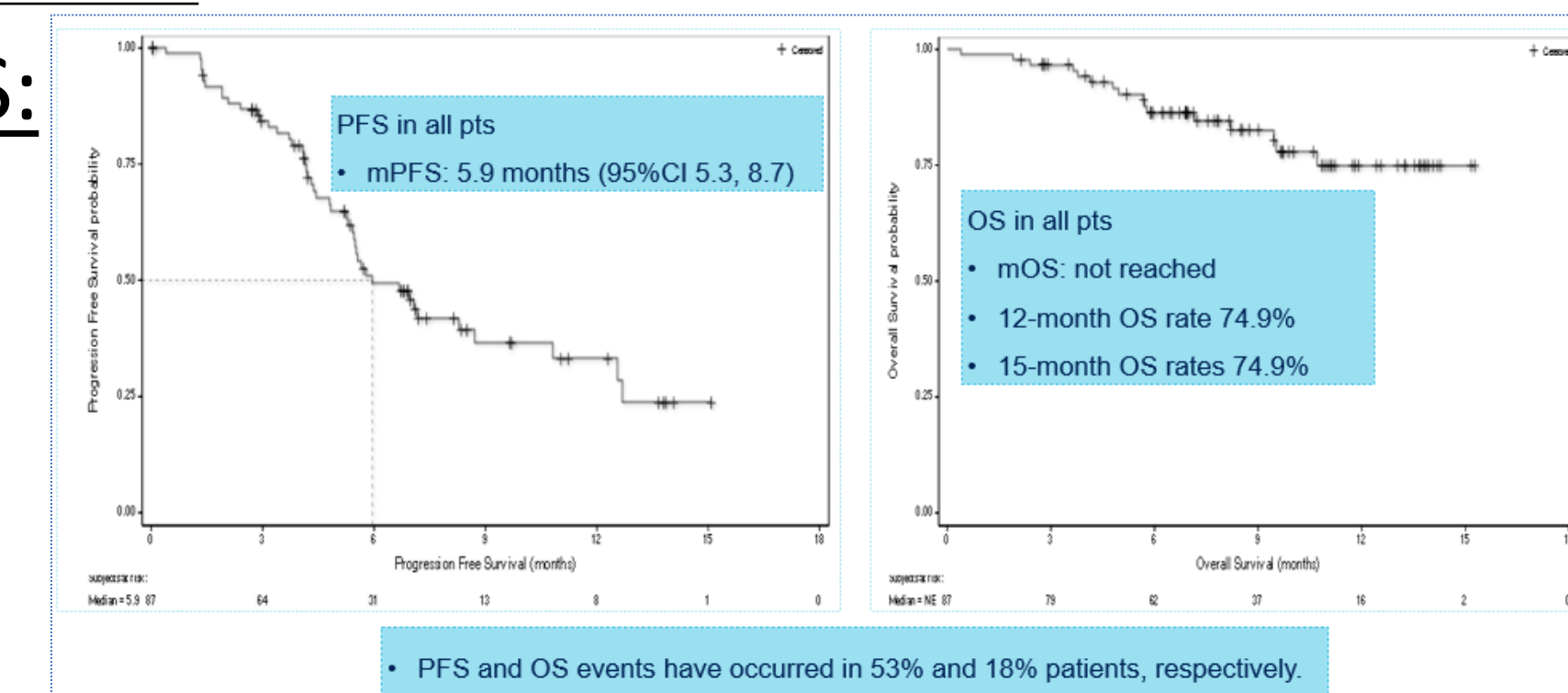
## irAE (Grade ≥ 3):

Preferred Term (CTCAE v5.0)	Grade ≥ 3
<b>Subjects with at least 1 CTCAE Grade ≥ 3 immune related AE</b>	<b>7 (8.0%)</b>
Dermatitis allergic	2 (2.3%)
Diarrhea	2 (2.3%)
Rash	2 (2.3%)
Alanine aminotransferase increase	1 (1.1%)
Aspartate aminotransferase increase	1 (1.1%)
Autoimmune hepatitis	1 (1.1%)
Bilirubin conjugated increased	1 (1.1%)
Immune-mediated pneumonitis	1 (1.1%)
Neutrophil count decreased	1 (1.1%)

## ORR/DCR:

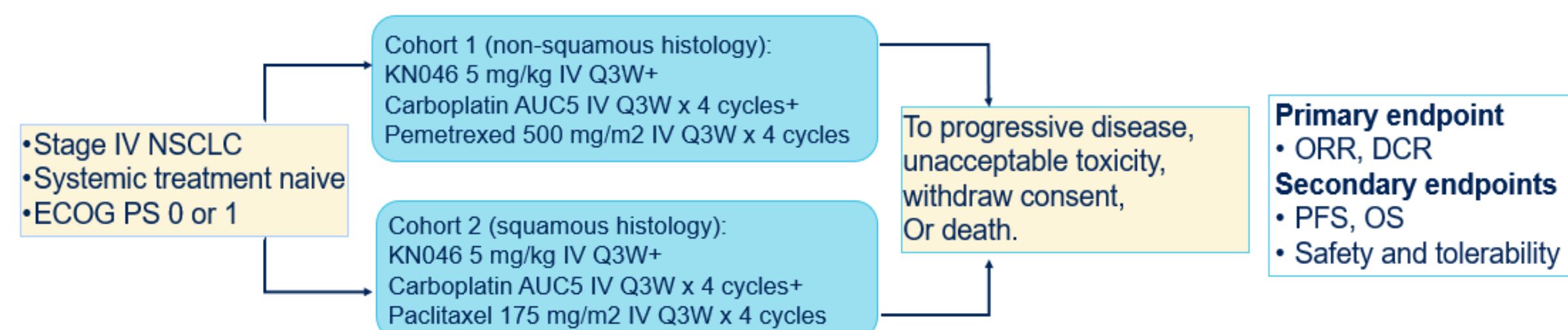


## PFS/OS:



## Methods:

- Efficacy evaluation was performed by investigators per RECIST 1.1.
- Safety and tolerability were assessed per NCI-CTCAE v5.0



## Future Directions for Research:

Pivotal Phase III trial in advanced unresectable or metastatic squamous NSCLC is currently ongoing.

## Conclusion:

KN046 combined with platinum doublet chemotherapy is tolerated and has shown promising clinical benefit as IL treatment for stage IV NSCLC particularly in PD-L1≥1% tumors and squamous histology.