CHOICE-01: A Phase 3 Study of Toripalimab versus Placebo In Combination with First-Line Chemotherapy for Advanced NSCLC

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Presenter DISCLOSURES

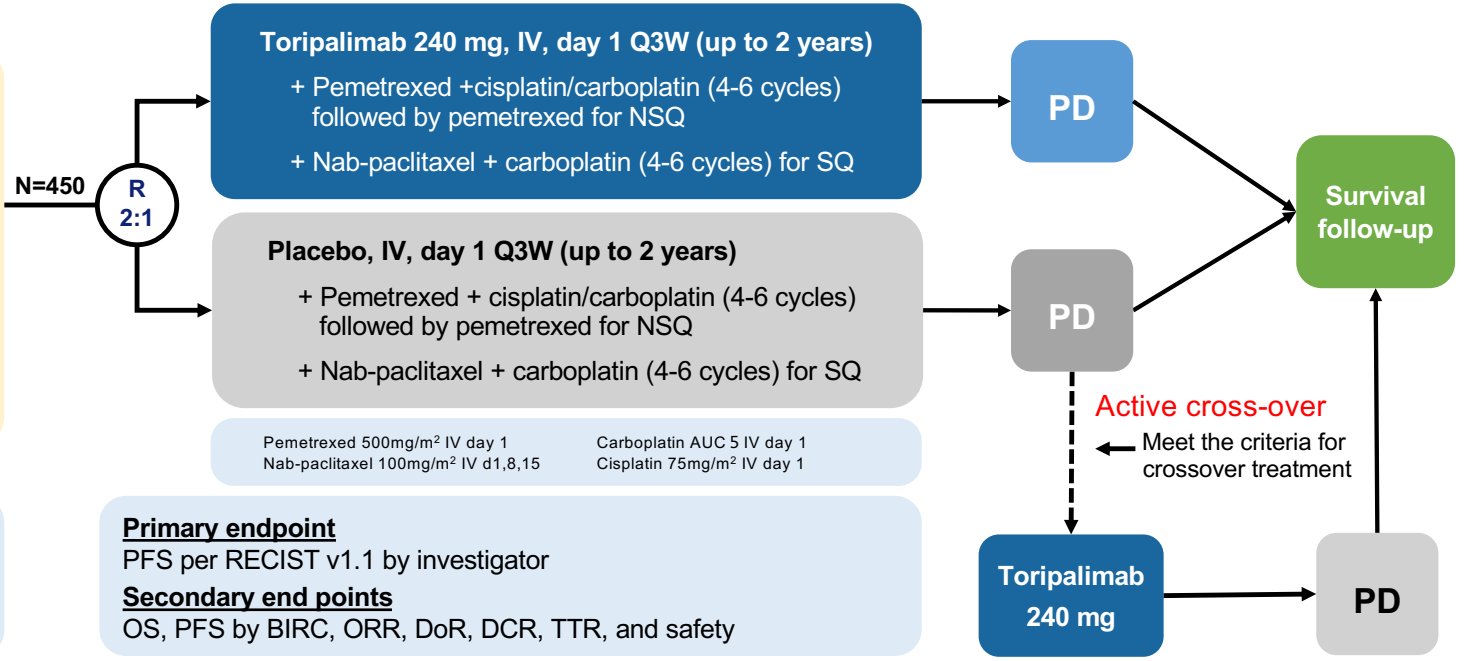
Prof. Jie WANG does not have any financial relationship to disclose.

CHOICE-01 Study Design

CHOICE-01 is a randomized, double-blind, placebo-controlled, multicenter, phase 3 trial comparing the efficacy and safety of toripalimab versus placebo in combination with first-line standard chemotherapy for treatment-naïve, advanced non-small cell lung cancer (NSCLC)

Key Eligibility Criteria

- Advanced NSCLC (SQ & NSQ)
  - Stage IIIB-IV
  - Treatment-naïve for locally advanced or metastatic setting
  - No known sensitizing EGFR mutation or ALK fusion
- Measurable disease per RECIST v1.1
- ECOG PS score 0-1
- Tumor tissue available for PD-L1 expression testing[1]



Stratification factors:

- PD-L1 expression (TC≥1% vs TC<1%)[2]
- Smoking status (often[3] vs never/occasional)
- Histology (squamous vs non-squamous)

Primary endpoint

PFS per RECIST v1.1 by investigator

Secondary end points

OS, PFS by BIRC, ORR, DoR, DCR, TTR, and safety

1 Based on JS311 IUO Assay
2 Patients with tumor unevaluable for PD-L1 included in TC<1% group
3 defined as ≥400 pack years

SQ=Squamous; NSQ=Non-Squamous;
BIRC= Blinded Independent Review Committee

Baseline Characteristics

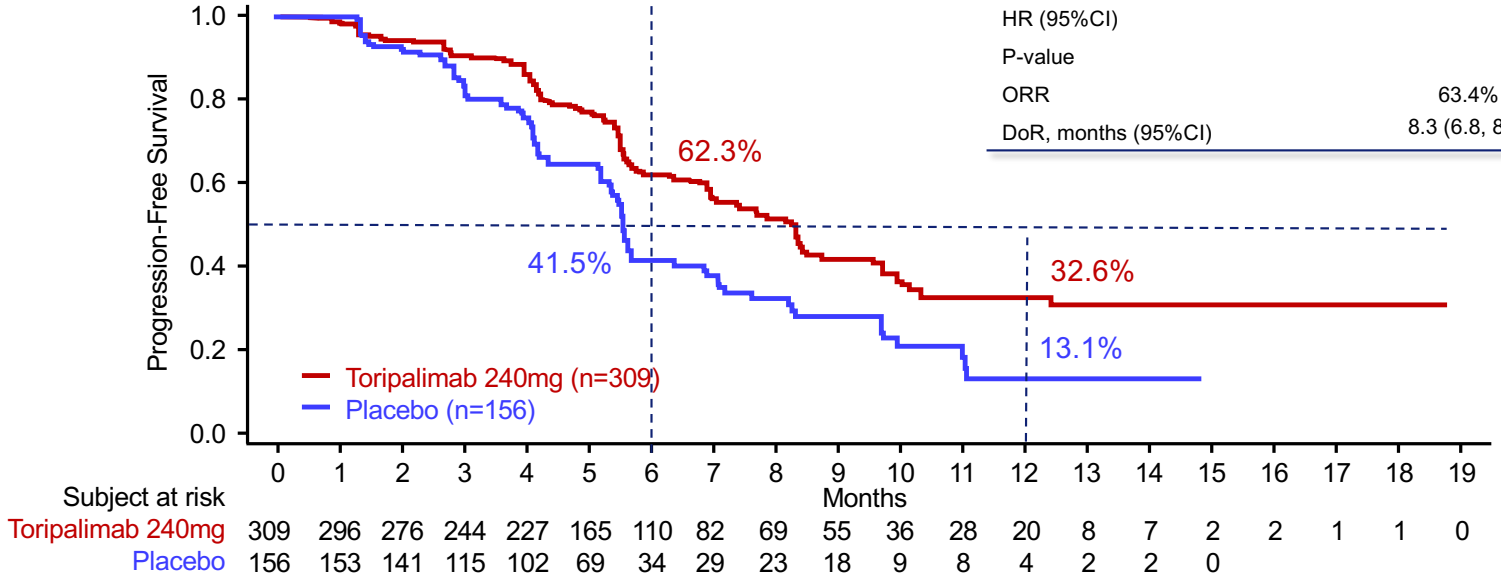
		Toripalimab+ Chemo (N=309)	Placebo+Chemo (N=156)
Age, Median (range), Years		63 (36 - 75)	61 (29 - 75)
Sex, Male, n(%)		247 (79.9)	130 (83.3)
ECOG	0	66 (21.4)	36 (23.1)
	1	243 (78.6)	120 (76.9)
Histology, n (%)	Squamous	147 (47.6)	73 (46.8)
	Non-squamous	162 (52.4)	83 (53.2)
PD-L1 expression, n (%)	TC ≥1%	201 (65.0)	103 (66.0)
	TC <1%	108 (35.0)	53 (34.0)
Smoking Status, n (%)	Frequent	213 (68.9)	107 (68.6)
	Never/Occasional	96 (31.1)	49 (31.4)
Stage at Study Entry[1], n (%)	IIIB/IIIC	49 (15.9)	23 (14.7)
	IVA	141 (45.6)	82 (52.6)
	IVB	119 (38.5)	51 (32.7)
Sites of Metastases, n (%)	Brain	5 (1.6)	0
	Liver	26 (8.4)	14 (9.0)
	≥3 metastatic sites	53 (17.2)	24 (15.4)
Prior Adjuvant/Neo-adjuvant therapy, n (%)		13 (4.2)	9 (5.8)

1. Based on AJCC 8th Edition

Data cut-off date: November 17th, 2020

Efficacy

PFS per RECIST v1.1 by Investigator

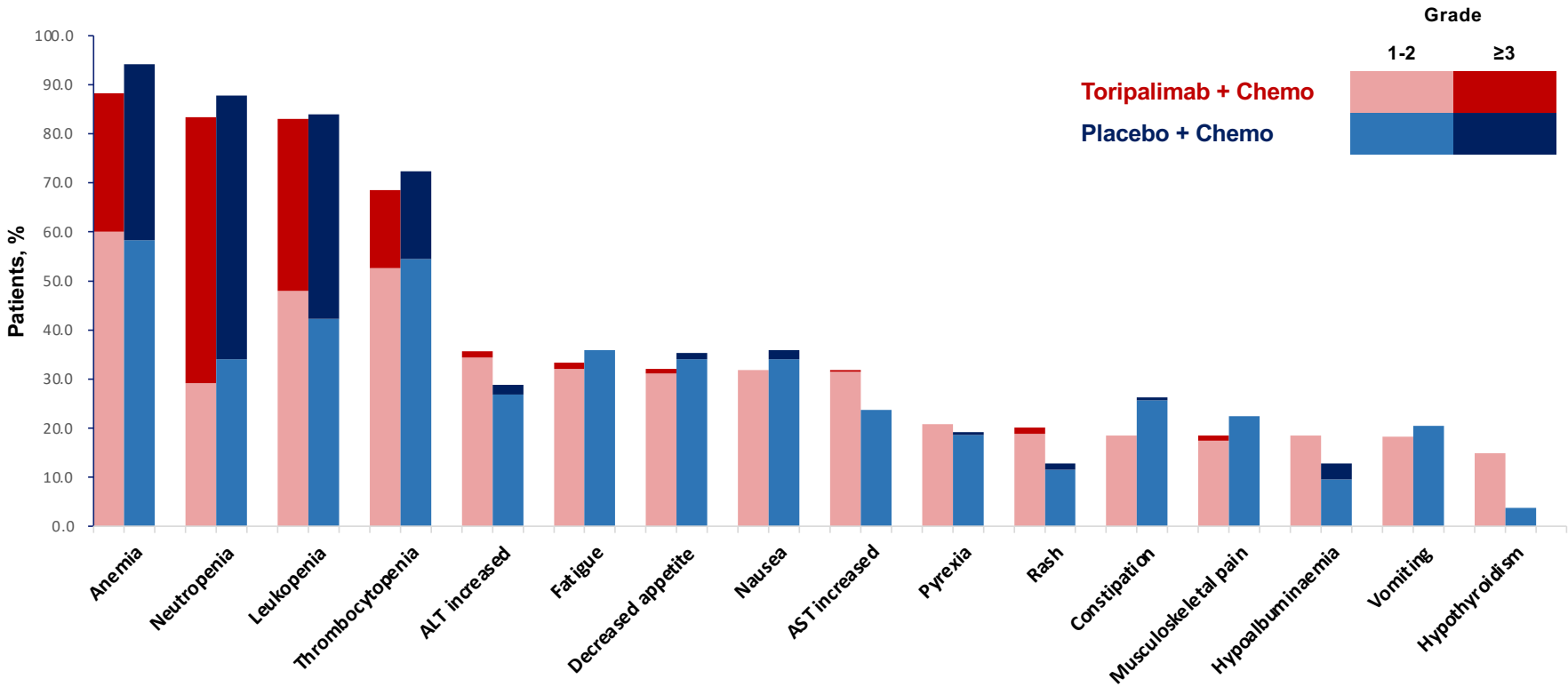


	Toripalimab +chemo (n=309)	Placebo + chemo (n=156)
Events (%)	130 (42.1)	88 (56.4)
Median PFS, months (95% CI)	8.3 (6.9-8.7)	5.6 (5.4-6.4)
HR (95%CI)	**0.58 (0.442-0.769)**	
P-value	0.0001	
ORR	63.4%	41.7%
DoR, months (95%CI)	8.3 (6.8, 8.7)	4.2 (4.0, 5.7)

- **PFS in squamous subgroup HR=0.55 (95% CI: 0.38-0.83); non-squamous subgroup HR=0.59 (95% CI: 0.40-0.87)**
- **IRC-assessed PFS for squamous and non-squamous patients was consistent with Investigator's assessed PFS**

Data cut-off date: November 17th, 2020

Most Frequent Treatment Emergent Adverse Events



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Summary

- CHOICE-01 is a randomized, double-blind, multicenter, phase 3 trial of toripalimab in combination with standard chemotherapy for 1st-line treatment of advanced squamous or non-squamous NSCLC.
- Toripalimab in combination with chemotherapy provided a significant improvement in PFS compared with chemotherapy alone.
  - mPFS: 8.3 vs 5.6 months, HR 0.58 (95%CI: 0.44-0.77), p=0.0001
  - Treatment effect on PFS was observed in both squamous and non-squamous patients, which was similar in magnitude to the ITT population. IRC-assessed PFS was consistent with investigator's assessment.
- Toripalimab in combination with chemotherapy had significant better ORR and DoR in the ITT population compared with chemotherapy alone as assessed by the investigator: ORR 63.4 vs 41.7, p<0.0001; DoR 8.3 vs 4.2 months. IRC assessed ORR and DoR had consistent results.
- As of March 7, 2021, OS was still immature with a trend favoring toripalimab: median OS 21.0 vs 16.0 months, HR 0.81 (95%CI: 0.57-1.17). Since patients in placebo arm actively crossed-over to toripalimab at disease progression, effects on OS may be confounded.
- The addition of toripalimab to standard 1st-line chemotherapy in patients with advanced NSCLC showed manageable safety profile with no new safety signal observed.

*Data cut-off: November 17th, 2020; survival data cut-off: March 11th, 2020