# Summit Therapeutics WCLC Update Call

September 8, 2025
8:00am ET

# Forward Looking Statement

Any statements in this press release about the Company's future expectations, plans and prospects, including but not limited to, statements about the clinical and preclinical development of the Company's product candidates, entry into and actions related to the Company's partnership with Akeso Inc., the Company's anticipated spending and cash runway, the therapeutic potential of the Company's product candidates, the potential commercialization of the Company's product candidates, the timing of initiation, completion and availability of data from clinical trials, the potential submission of applications for marketing approvals, potential acquisitions, statements about the previously disclosed At-The-Market equity offering program ("ATM Program"), the expected proceeds and uses thereof, the Company's estimates regarding stock-based compensation, and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the Company's ability to sell shares of our common stock under the ATM Program, the conditions affecting the capital markets, general economic, industry, or political conditions, the results of our evaluation of the underlying data in connection with the development and commercialization activities for ivonescimab, the outcome of discussions with regulatory authorities, including the Food and Drug Administration, the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials, the results of such trials, and their success, global public health crises, that may affect timing and status of our clinical trials and operations, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials or preclinical studies will be indicative of the results of later clinical trials, whether business development opportunities to expand the Company's pipeline of drug candidates, including without limitation, through potential acquisitions of, and/or collaborations with, other entities occur, expectations for regulatory approvals, laws and regulations affecting government contracts and funding awards, availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of filings that the Company makes with the Securities and Exchange Commission. Any change to our ongoing trials could cause delays, affect our future expenses, and add uncertainty to our commercialization efforts, as well as to affect the likelihood of the successful completion of clinical development of ivonescimab. Accordingly, readers should not place undue reliance on forward-looking statements or information. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of this release and should not be relied upon as representing the Company's views as of any subsequent date. The Company specifically disclaims any obligation to update any forward-looking statements included in this press release.

HARMONi

# Ivonescimab vs Placebo Plus Chemo, Phase 3 in Patients with EGFR+ NSCLC Progressed with 3rd gen EGFR-TKI Treatment: HARMONi

**Jonathan W. Goldman[1], Antonio Passaro[2], Janessa Laskin[3], Delvys Rodrigues-Abreu[4], Antonio Calles[5], Lyudmila Bazhenova[6], Giuseppe Lo Russo[7], Natasha Leighl[8], Frederico Cappuzzo[9], Nicolas Girard[10], Sanjay Popat[11], Wenfeng Fang[12], Yongzhong Luo[13], Runxiang Yang[14], Wenting Li[15], Jianling Li[16], Lori Styles[16], Benjamin Thompson[16], Li Zhang[17], Xiuning Le[18].**

[1]UCLA Health, Santa Monica, CA, USA; [2]European Institute of Oncology, Milan, Italy; [3]British Columbia Cancer Research Institute, Vancouver, Canada; [4]Universidad de Las Palmas de Gran Canaria, Las Palmas de Gran Canaria, Spain; [5]Hospital General Universitario Gregorio Marañón, Madrid, Spain; [6]UC San Diego Moores Cancer Center, San Diego, CA, USA; [7]Fondazione IRCCS Istituto Nazionale Tumori, Milan, Italy; [8]Princess Margaret Cancer Centre University of Toronto, Toronto, Ontario, Canada; [9]Regina Elena National Cancer Institute, Rome, Italy; [10]Institut Curie, Paris, France; [11]Lung Unit, Royal Marsden Hospital, London, UK; [12]Sun Yat-sen University Cancer Center, Guangzhou, China; [13]Hunan Cancer Hospital, Changsha, China; [14]Yunnan Cancer Hospital, Kunming, China; [15]Akeso Biopharma, Inc., Zhongshan, China; [16]Summit Therapeutics, Menlo Park, CA, USA; [17]Sun Yat-sen University Cancer Center, Guangzhou, China; [18]The University of Texas MD Anderson Cancer Center, Houston, TX, USA.



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# Phase 3 Study Design

HARMONi

## Key Eligibility Criteria

Locally advanced or metastatic NSCLC:

- EGFR sensitizing mutation+
- Progressed on 3rd gen EGFR-TKI
- ECOG 0 or 1
- Any PD-L1 expression

**Stratification factor by geographic region:**

- Brain metastases (yes or no)


N=438

**Ivonescimab + Chemotherapy**
(N = 219)

**Placebo + Chemotherapy**
(N = 219)

**Ivonescimab**: 20 mg/kg Q3W

**Chemotherapy**:

- Carboplatin: AUC5 Q3W x 4 cycles (21 day/cycle)
- Pemetrexed: 500 mg/m$^2$ Q3W

## Endpoints:

**Primary**

- OS, PFS by IRRC per RECIST 1.1

**Secondary**

- ORR by IRRC, DoR, safety and tolerability

## Planned Efficacy Analyses

- PFS primary (at ~231 events) & OS interim analyses
- OS final analysis (at ~261 events)

FPI: Jan 2022 (overall)
LPI Asia: Nov 2022
LPI NA & EU (and overall): Oct 2024

DoR=duration of response; ECOG=eastern cooperative oncology group; EGFR= Epidermal growth factor receptor; EU=Europe; FPI=first patient in; IRRC= independent radiology review committee; LPI=last patient in; mets=metastases; NA=North America; ORR=overall response rate; OS=overall survival; NSCLC=non-small cell lung cancer; TKI=tyrosine kinase inhibitor; PD-L1= programmed cell death ligand; PFS=progression-free survival; Q3W=every 3 weeks; RECIST=response evaluation criteria in solid tumors.

Note: Positive outcomes were reported from the single-region (Asia) study HARMONi-A, with PFS as the primary endpoint.



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# Background

HARMONi

## Global Enrollment Time Period:

| | |
|---|---|
| Asia: | Jan 2022 – Nov 2022 |
| Western: | May 2023 – Oct 2024 |

## Timing of Global Analyses:

| | |
|---|---|
| PFS Primary Analysis: | Jul 2024 |
| PFS Total Analysis: | Apr 2025 |
| OS Primary Analysis: | Apr 2025 |
| OS Longer-term FU of Western pts* Analysis: | Sep 2025 |

**For longer-term analysis for OS, western patients were followed to increase time on study; Asian patients were locked at the time of the primary OS analysis, having >30 mos of median FU time.*

PFS = progression-free survival; OS = overall survival; FU = follow-up



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# Phase 3 Study Design

HARMONi

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# Demographic and Baseline Characteristics

## Arms were well-balanced; majority were females, ECOG 1, never smokers; 25% with brain mets

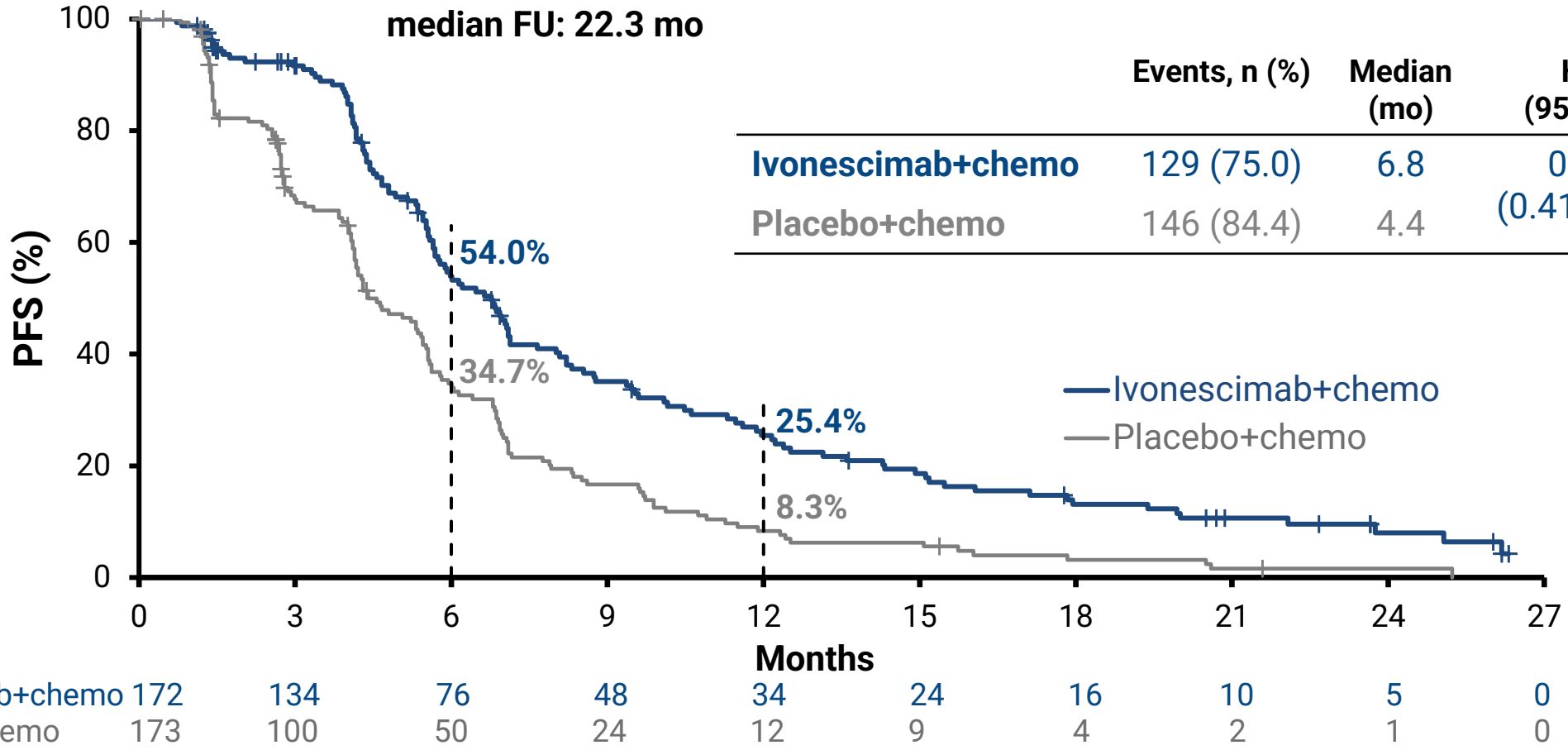
| Characteristic, n (%) | Ivonescimab+chemo (N=219) | Placebo+chemo (N=219) |
|---|---|---|
| **Age – Median (range)** | 62 (32-84) | 60 (36-84) |
| ≥65 yr | 83 (37.9) | 88 (40.2) |
| **Female** | 130 (59.4) | 127 (58.0) |
| **Region – NA & Europe** | 83 (37.9) | 82 (37.4) |
| **Asia** | 136 (62.1) | 137 (62.6) |
| **Race – Asian** | 153 (69.9) | 153 (69.9) |
| **White** | 51 (23.3) | 54 (24.7) |
| **ECOG - 1** | 162 (74.0) | 157 (71.7) |
| **Smoking - Never** | 143 (65.3) | 155 (70.8) |
| **Stage - IV** | 215 (98.2) | 214 (97.7) |
| **Brain metastasis** | 54 (24.7) | 54 (24.7) |
| **Liver metastasis** | 32 (14.6) | 23 (10.5) |
| **Prior line of systemic cancer therapy (median)** | 1.0 | 1.0 |
| **Prior EGFR-TKI** | | |
| 1st/2nd generation | 95 (43.4) | 92 (42.0) |
| 3rd generation | 219 (100) | 218 (99.5) |
| 4th generation | 1 (0.5) | 0 |
| **EGFR Mutation** | | |
| 19del | 131 (59.8) | 118 (53.9) |
| L858R | 74 (33.8) | 90 (41.1) |
| Non-19del/L858R* | 15 (6.8) | 11 (5.0) |

* Non-19del/L858R mutations include G719X, L861Q, S768I, etc.

ECOG=eastern cooperative oncology group; EGFR= Epidermal growth factor receptor; TKI=tyrosine kinase inhibitor.

# Primary Endpoint: PFS by IRRC

## Statistically significant and clinically meaningful benefit with ivonescimab




| | Events, n (%) | Median (mo) | HR (95% CI) | *P* Value |
|---|---|---|---|---|
| **Ivonescimab+chemo** | 129 (75.0) | 6.8 | 0.52 (0.41-0.66) | <0.0001 |
| **Placebo+chemo** | 146 (84.4) | 4.4 | | |

**No. at risk**

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Ivonescimab+chemo | 172 | 134 | 76 | 48 | 34 | 24 | 16 | 10 | 5 | 0 |
| Placebo+chemo | 173 | 100 | 50 | 24 | 12 | 9 | 4 | 2 | 1 | 0 |

**Consistent PFS benefit by investigator: HR = 0.58 (95% CI: 0.45-0.73)**

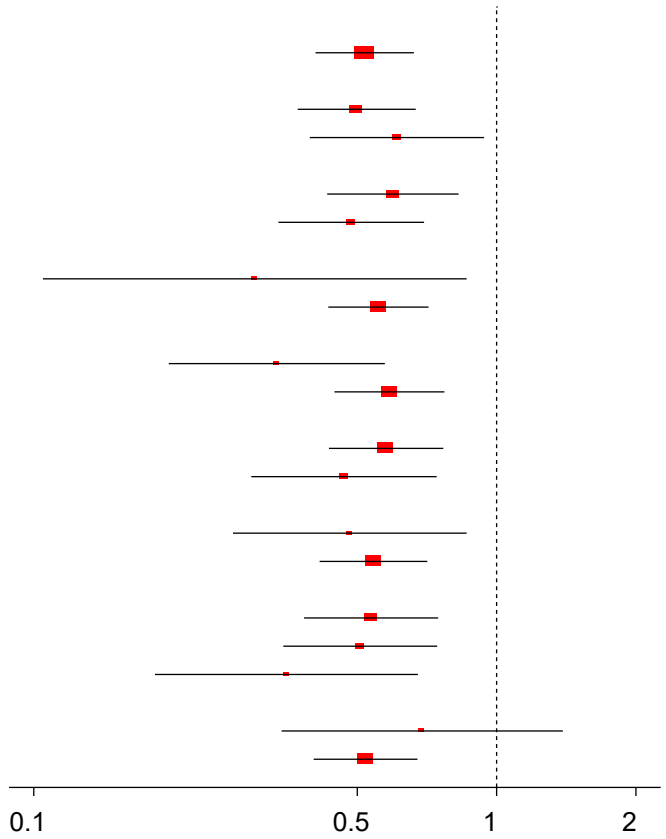
CI=confidence interval; FU=follow-up; HR=hazard ratio; IRRC= independent radiology review committee; PFS=progression-free survival.

# PFS by IRRC – Subgroup Analysis

## Consistent across pre-defined subgroups

HARMONi

| | Ivonescimab + chemo (Events/N) | Placebo + chemo (Events/N) | Hazard Ratio (95% CI) |
|---|---|---|---|
| **Overall population** | 129/172 | 146/173 | 0.52 (0.41-0.66) |
| **Age** | | | |
| <65 years | 89/115 | 101/110 | 0.50 (0.37-0.67) |
| >=65 years | 40/57 | 45/63 | 0.61 (0.39-0.94) |
| **Sex** | | | |
| Female | 74/97 | 74/92 | 0.60 (0.43-0.83) |
| Male | 55/75 | 72/81 | 0.49 (0.34-0.70) |
| **Geographic region** | | | |
| NA & EU | 6/36 | 12/36 | 0.30 (0.10-0.86) |
| Asia | 123/136 | 134/137 | 0.56 (0.43-0.71) |
| **Brain metastases prior to study entry** | | | |
| Present | 28/41 | 34/42 | 0.34 (0.20-0.57) |
| Absent | 101/131 | 112/131 | 0.59 (0.45-0.77) |
| **Smoking history** | | | |
| Never | 95/117 | 101/121 | 0.58 (0.43-0.77) |
| Former/Current | 34/55 | 45/52 | 0.47 (0.30-0.74) |
| **Baseline ECOG performance status** | | | |
| 0 | 19/35 | 33/43 | 0.48 (0.27-0.86) |
| 1 | 110/137 | 113/130 | 0.54 (0.41-0.71) |
| **Baseline EGFR mutation** | | | |
| 19Del | 77/104 | 69/86 | 0.54 (0.38-0.75) |
| L858R | 45/56 | 73/78 | 0.51 (0.35-0.74) |
| T790M | 25/27 | 17/21 | 0.35 (0.18-0.68) |
| **Liver metastases prior to study entry** | | | |
| Present | 19/26 | 15/20 | 0.69 (0.34-1.39) |
| Absent | 110/146 | 131/153 | 0.52 (0.40-0.67) |




ECOG=eastern cooperative oncology group; EGFR= Epidermal growth factor receptor; IRRC= independent radiology review committee; PFS=progression-free survival; PS=performance status; TKI=tyrosine kinase inhibitor.



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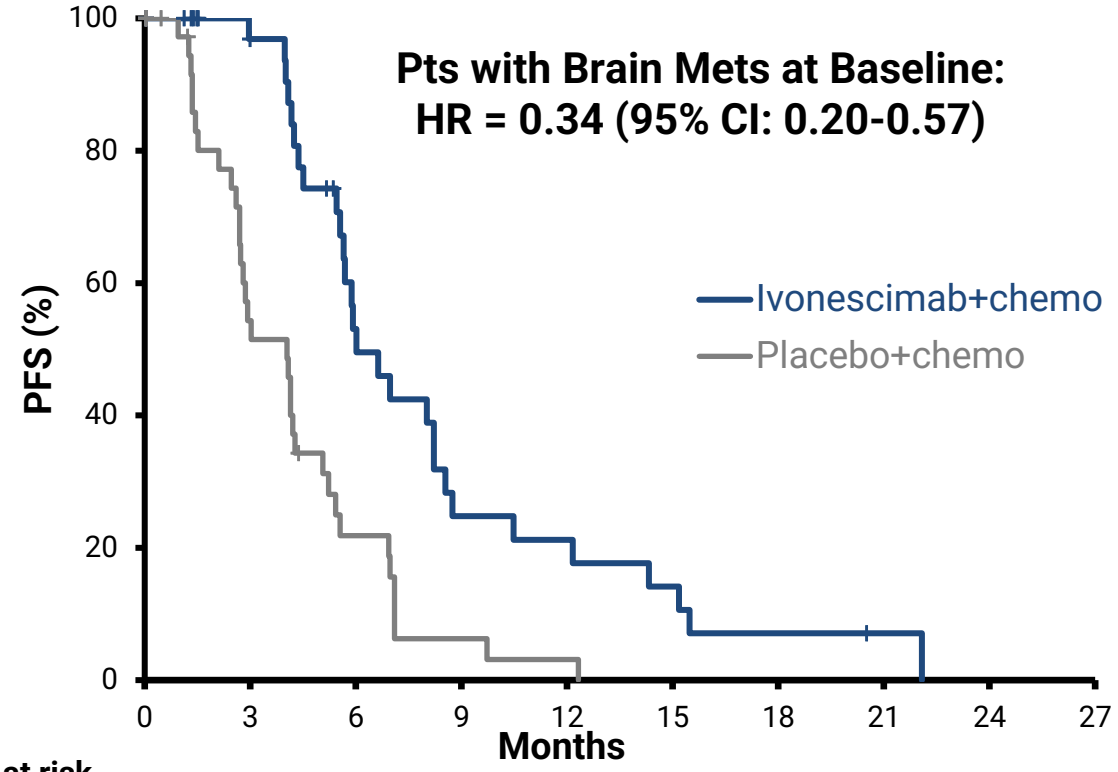
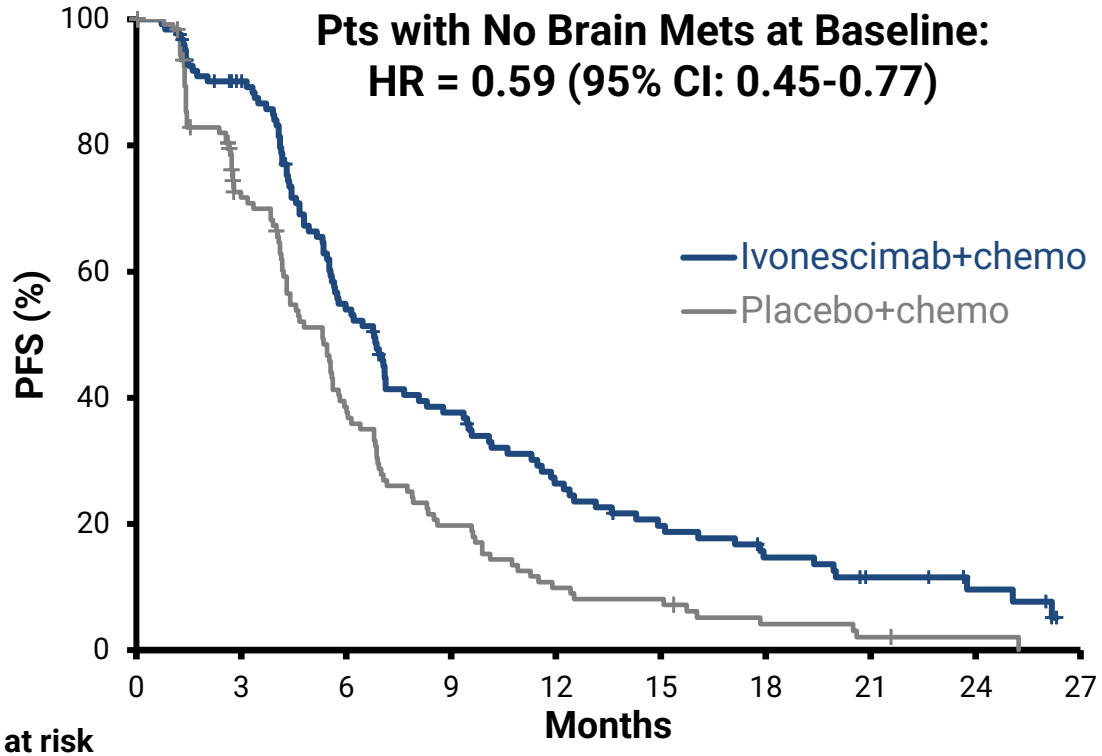
# PFS by Presence or Absence of Brain Mets

HARMONi




| No. at risk | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Ivonescimab +chemo | 41 | 30 | 15 | 7 | 6 | 4 | 2 | 1 | 0 |
| Placebo +chemo | 42 | 19 | 7 | 2 | 1 | 0 | | | |




| No. at risk | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Ivonescimab +chemo | 131 | 104 | 61 | 41 | 28 | 20 | 14 | 9 | 5 | 0 |
| Placebo +chemo | 131 | 81 | 43 | 22 | 11 | 9 | 4 | 2 | 1 | 0 |

CI=confidence interval; HR=hazard ratio; PFS=progression-free survival; pts=patients.



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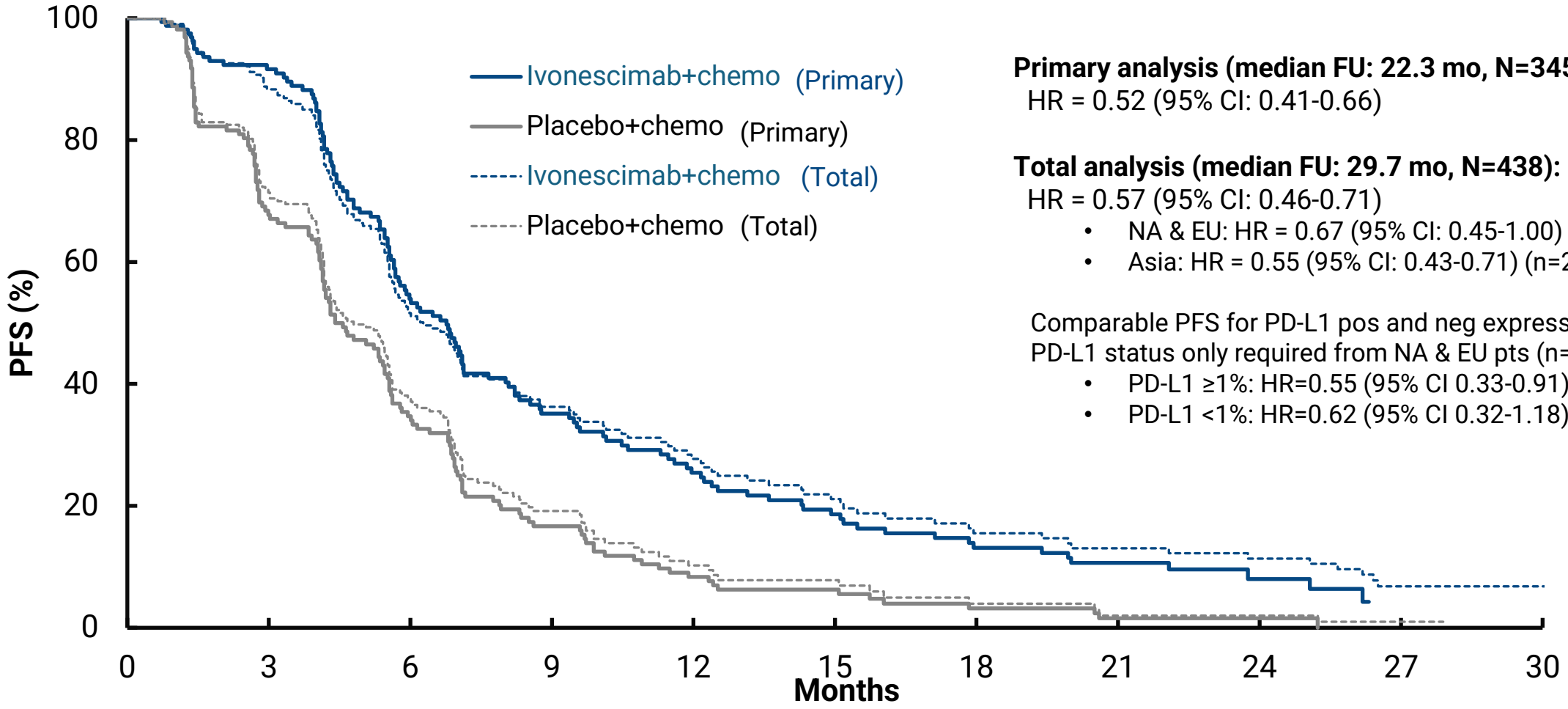
# PFS by IRRC: Primary Analysis vs Total PFS Analysis

## Consistent PFS with Primary and Total (All Patients) PFS Analysis including all NA & EU patients




**Primary analysis (median FU: 22.3 mo, N=345):**
HR = 0.52 (95% CI: 0.41-0.66)

**Total analysis (median FU: 29.7 mo, N=438):**
HR = 0.57 (95% CI: 0.46-0.71)

- NA & EU: HR = 0.67 (95% CI: 0.45-1.00) (n=165)
- Asia: HR = 0.55 (95% CI: 0.43-0.71) (n=273)

Comparable PFS for PD-L1 pos and neg expression.
PD-L1 status only required from NA & EU pts (n=160):

- PD-L1 ≥1%: HR=0.55 (95% CI 0.33-0.91) (n=106)
- PD-L1 <1%: HR=0.62 (95% CI 0.32-1.18) (n=54)

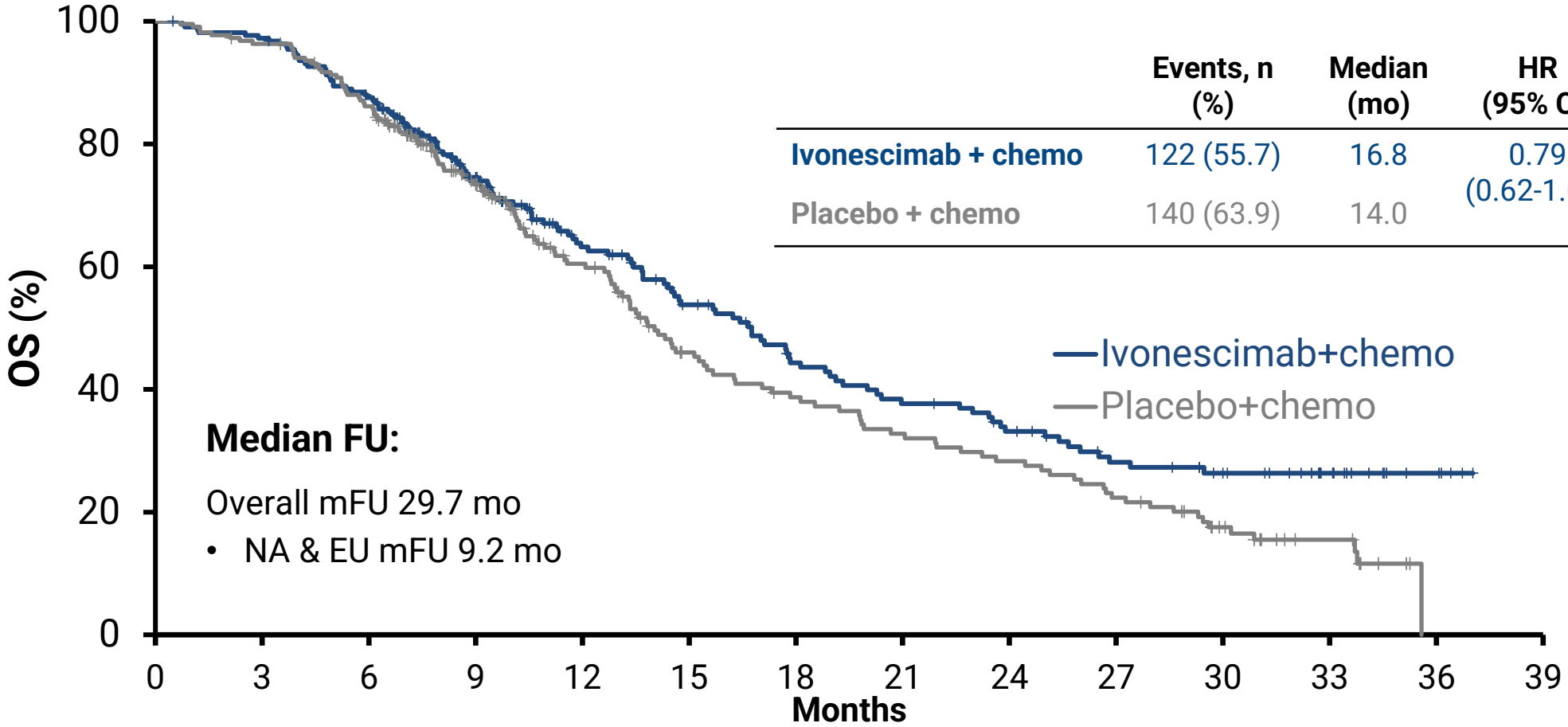
CI=confidence interval; EU=Europe; FU=follow-up; HR=hazard ratio; IRRC=independent radiographic review committee; NA=North America; PD-L1= programmed cell death ligand; PFS=progression-free survival.

# Primary Endpoint: Overall Survival

## Favorable Trend Observed; NA & EU Follow-up Not Yet Mature

### No detrimental impact on any predefined subgroups

| | Events, n (%) | Median (mo) | HR (95% CI) | *P* Value |
|---|---|---|---|---|
| **Ivonescimab + chemo** | 122 (55.7) | 16.8 | 0.79 (0.62-1.01) | 0.0570 |
| **Placebo + chemo** | 140 (63.9) | 14.0 | | |




**No. at risk**

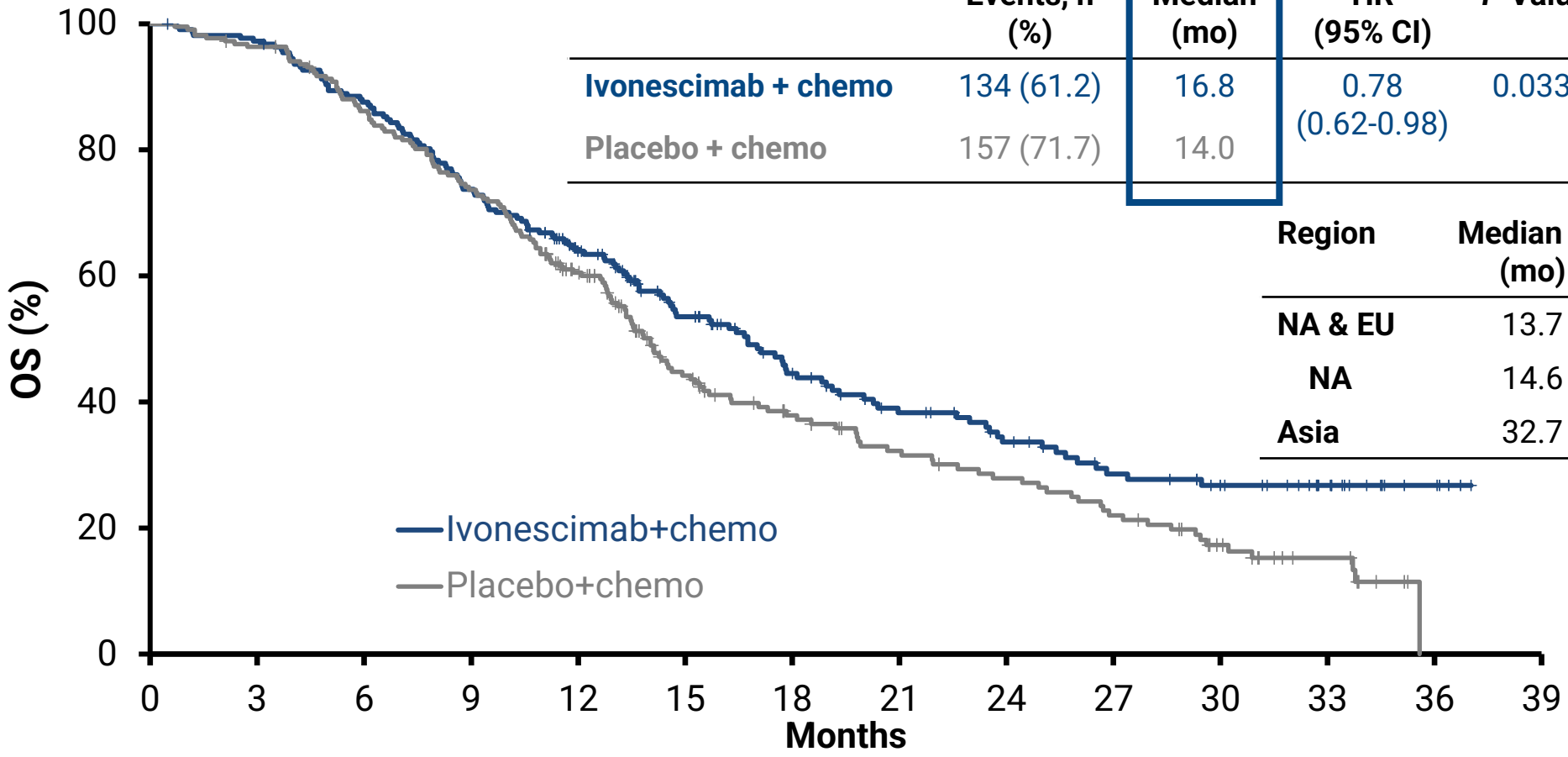
| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ivonescimab+chemo | 219 | 212 | 189 | 137 | 98 | 77 | 60 | 51 | 43 | 33 | 26 | 16 | 5 | 0 |
| Placebo+chemo | 219 | 210 | 186 | 132 | 92 | 63 | 52 | 44 | 38 | 30 | 18 | 9 | 0 | |

CI=confidence interval; EU=Europe; FU=follow-up; HR=hazard ratio; NA=North America; OS=overall survival.

# Overall Survival: Longer Term Western Follow-up

## OS stable with longer term Western Data, nominal p=0.0332

| | Events, n (%) | Median (mo) | HR (95% CI) | *P* Value |
|---|---|---|---|---|
| **Ivonescimab + chemo** | 134 (61.2) | 16.8 | 0.78 (0.62-0.98) | 0.0332 |
| **Placebo + chemo** | 157 (71.7) | 14.0 | | |




| Region | Median FU (mo) | Median OS (mo) |
|---|---|---|
| **NA & EU** | 13.7 | 17.0 vs. 14.0 |
| **NA** | 14.6 | NR vs. 14.0 |
| **Asia** | 32.7 | 16.7 vs. 14.0 |

Data cutoff
NA&EU: Sep 2025
Asia: Apr 2025

**No. at risk**

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ivonescimab+chemo | 219 | 212 | 190 | 160 | 127 | 92 | 68 | 53 | 43 | 33 | 26 | 16 | 5 | 0 |
| Placebo+chemo | 219 | 210 | 186 | 159 | 119 | 74 | 56 | 45 | 38 | 30 | 18 | 9 | 0 | |

Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA).

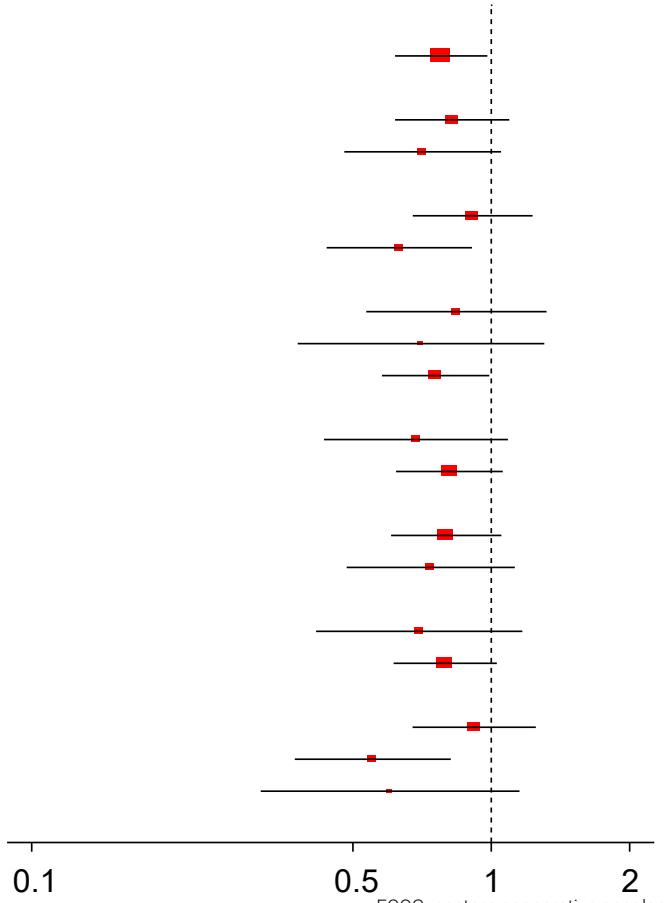
CI=confidence interval; EU=Europe; FU=follow-up; HR=hazard ratio; NA=North America; OS=overall surv… mo=months.

# Overall Survival Subgroup Analysis – Longer Term FU

## Consistent across pre-defined subgroups

HARMONi

| | Ivonescimab + chemo (Events/N) | Placebo + chemo (Events/N) | Hazard Ratio (95% CI) |
|---|---|---|---|
| **Overall population** | 134/219 | 157/219 | 0.78 (0.62-0.98) |
| **Age** | | | |
| <65 years | 90/136 | 99/131 | 0.82 (0.62-1.09) |
| >=65 years | 44/83 | 58/88 | 0.71 (0.48-1.05) |
| **Sex** | | | |
| Female | 84/130 | 87/127 | 0.91 (0.67-1.23) |
| Male | 50/89 | 70/92 | 0.63 (0.44-0.91) |
| **Geographic region** | | | |
| NA & EU | 36/83 | 40/82 | 0.84 (0.53-1.32) |
| NA* | 17/43 | 25/50 | 0.70 (0.38-1.30) |
| Asia | 98/136 | 117/137 | 0.76 (0.58-0.99) |
| **Brain metastases prior to study entry** | | | |
| Present | 33/54 | 41/54 | 0.69 (0.43-1.09) |
| Absent | 101/165 | 116/165 | 0.81 (0.62-1.06) |
| **Smoking history** | | | |
| Never | 92/143 | 112/155 | 0.80 (0.61-1.05) |
| Former/Current | 42/76 | 45/64 | 0.74 (0.48-1.13) |
| **Baseline ECOG performance status** | | | |
| 0 | 24/57 | 36/62 | 0.70 (0.42-1.17) |
| 1 | 110/162 | 121/157 | 0.79 (0.61-1.03) |
| **Baseline EGFR mutation** | | | |
| 19Del | 84/131 | 78/118 | 0.92 (0.67-1.25) |
| L858R | 39/74 | 73/90 | 0.55 (0.37-0.82) |
| T790M | 19/29 | 18/25 | 0.60 (0.31-1.15) |




*Provided for informational purposes; not a predefined subgroup*

ECOG=eastern cooperative oncology group; EGFR= Epidermal growth factor receptor;, NA = North America, EU = Europe, PS=performance status; TKI=tyrosine kinase inhibitor.

# Reminder: Background

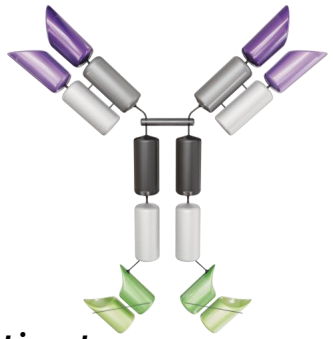
HARMONi

## Global Enrollment Time Period:

| | |
|---|---|
| Asia: | Jan 2022 – Nov 2022 |
| Western: | May 2023 – Oct 2024 |

## Timing of Global Analyses:

| | |
|---|---|
| PFS Primary Analysis: | Jul 2024 |
| PFS Total Analysis: | Apr 2025 |
| OS Primary Analysis: | Apr 2025 |
| OS Longer-term FU of Western pts* Analysis: | Sep 2025 |



**For longer-term analysis for OS, western patients were followed to increase time on study; Asian patients were locked at the time of the primary OS analysis, having >30 mos of median FU time.*

PFS = progression-free survival; OS = overall survival; FU = follow-up



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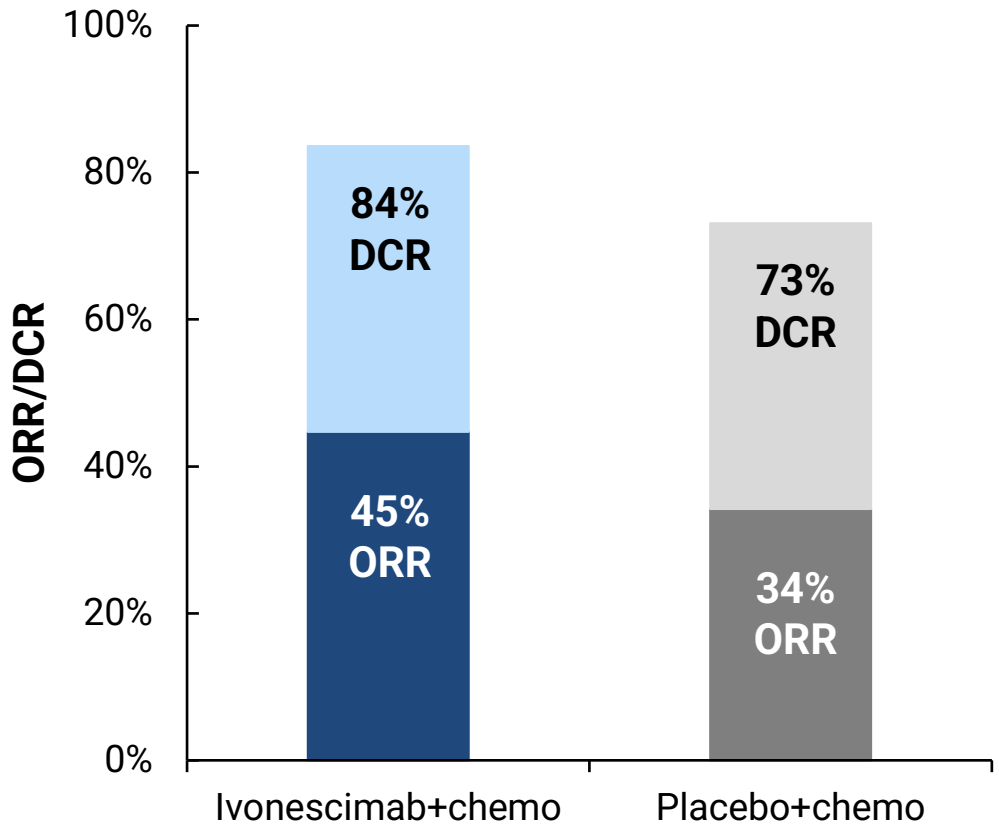
# Overall Response Rate and Duration of Response

## By IRRC




| DoR (mo) | Ivonescimab + chemo | Placebo + chemo |
|---|---|---|
| n | 98 | 75 |
| Median (95% CI) | **7.6** (5.5-10.6) | **4.2** (2.9-4.7) |

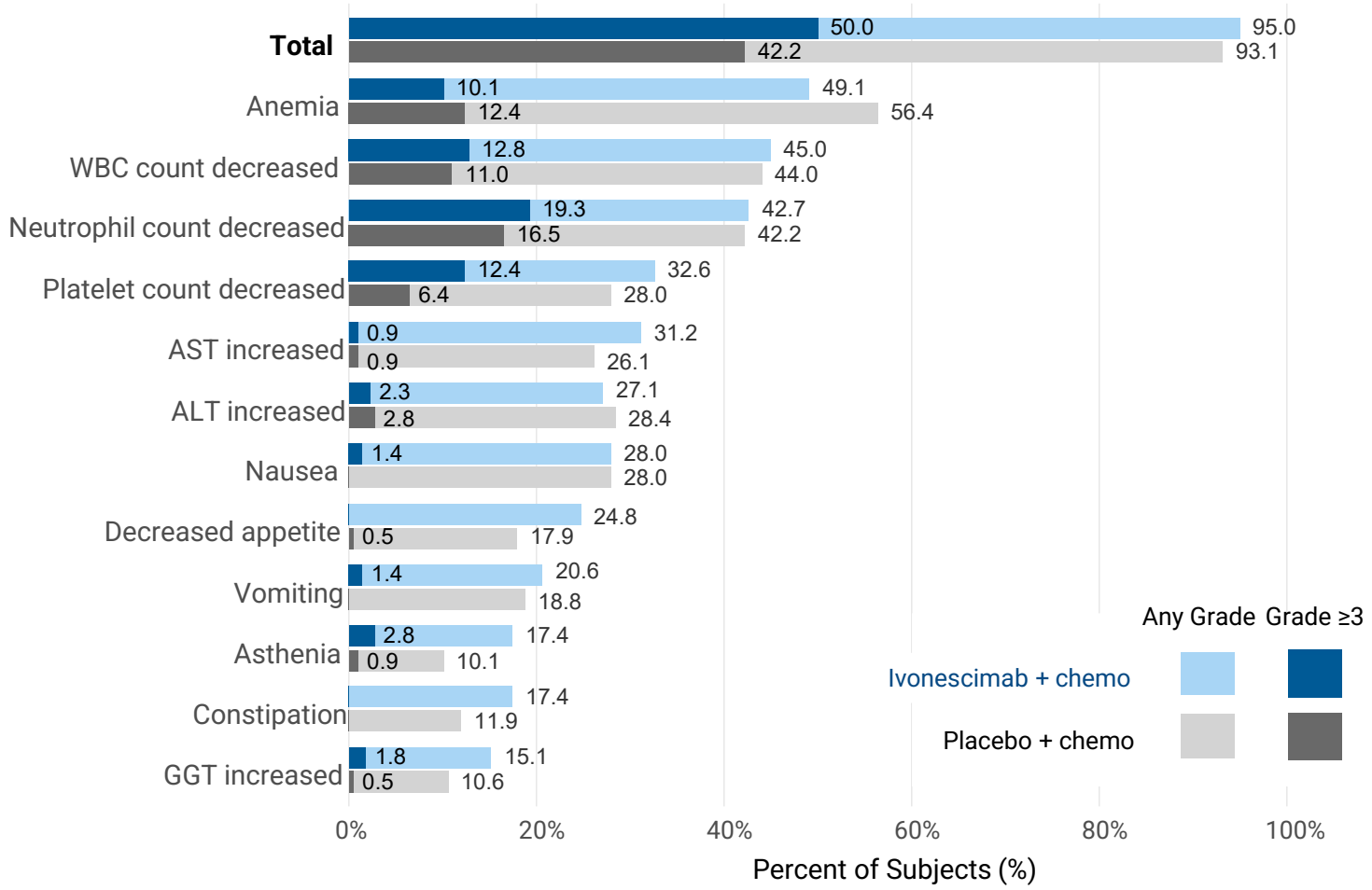
CI=confidence interval; DCR=disease control rate; DoR=duration of response; ORR=overall response rate; IRRC= independent radiographic review committee.

# Treatment-Related Adverse Events (TRAEs)

## Most common were lab abnormalities, nausea, decreased appetite

| TRAE, n(%) | Ivonescimab + chemo (N=218) | Placebo + chemo (N=218) |
|---|---|---|
| **Any Grade** | 207 (95.0) | 203 (93.1) |
| **Grade ≥3** | 109 (50.0) | 92 (42.2) |
| **Serious** | 61 (28.0) | 33 (15.1) |
| **Led to d/c of ivonescimab/placebo** | 16 (7.3) | 11 (5.0) |
| **Led to death** | 4 (1.8) | 5 (2.3) |
| **Grade ≥3 irAE** | 21 (9.6) | 13 (6.0) |
| **Grade ≥3 VEGF-related** | 16 (7.3) | 7 (3.2) |

One patient in each treatment arm did not receive study drug

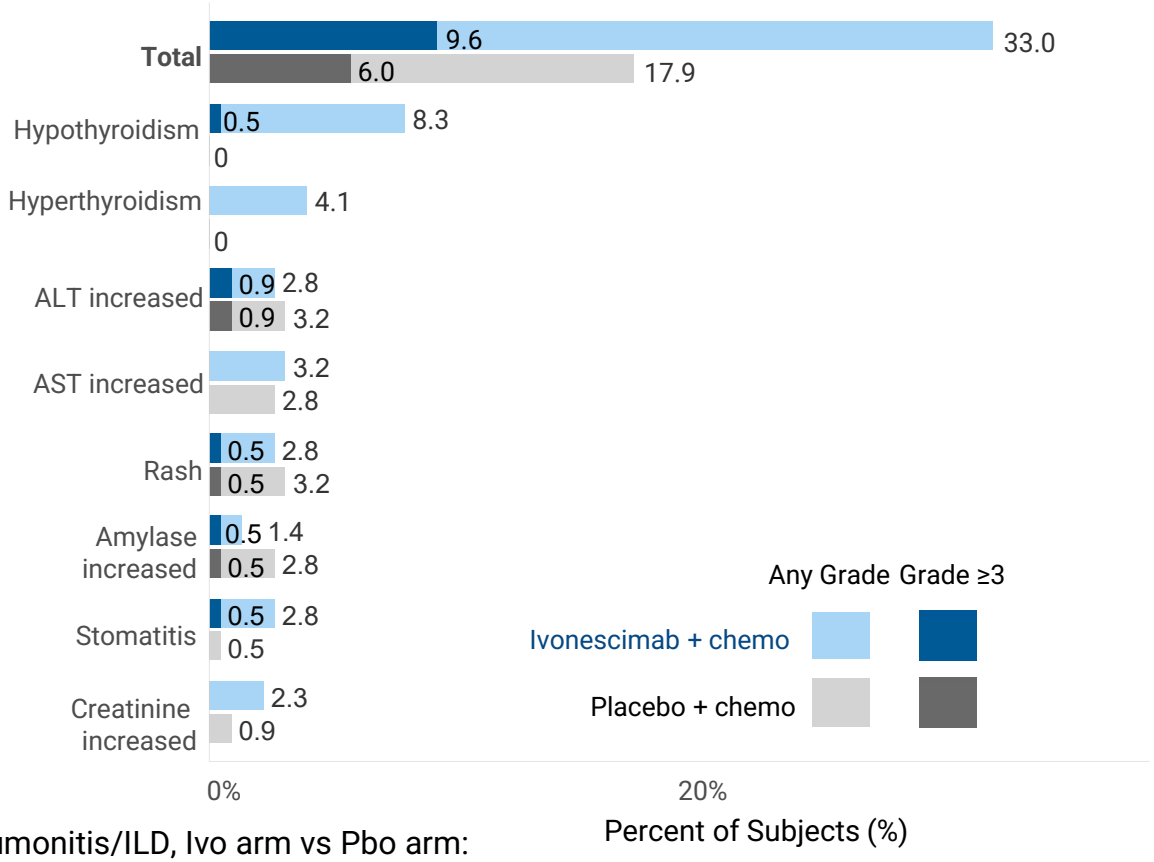



d/c=discontinuation; irAE=immune-related adverse events; VEGF= vascular endothelial growth factor.

# Immune-related and VEGF-related TRAEs

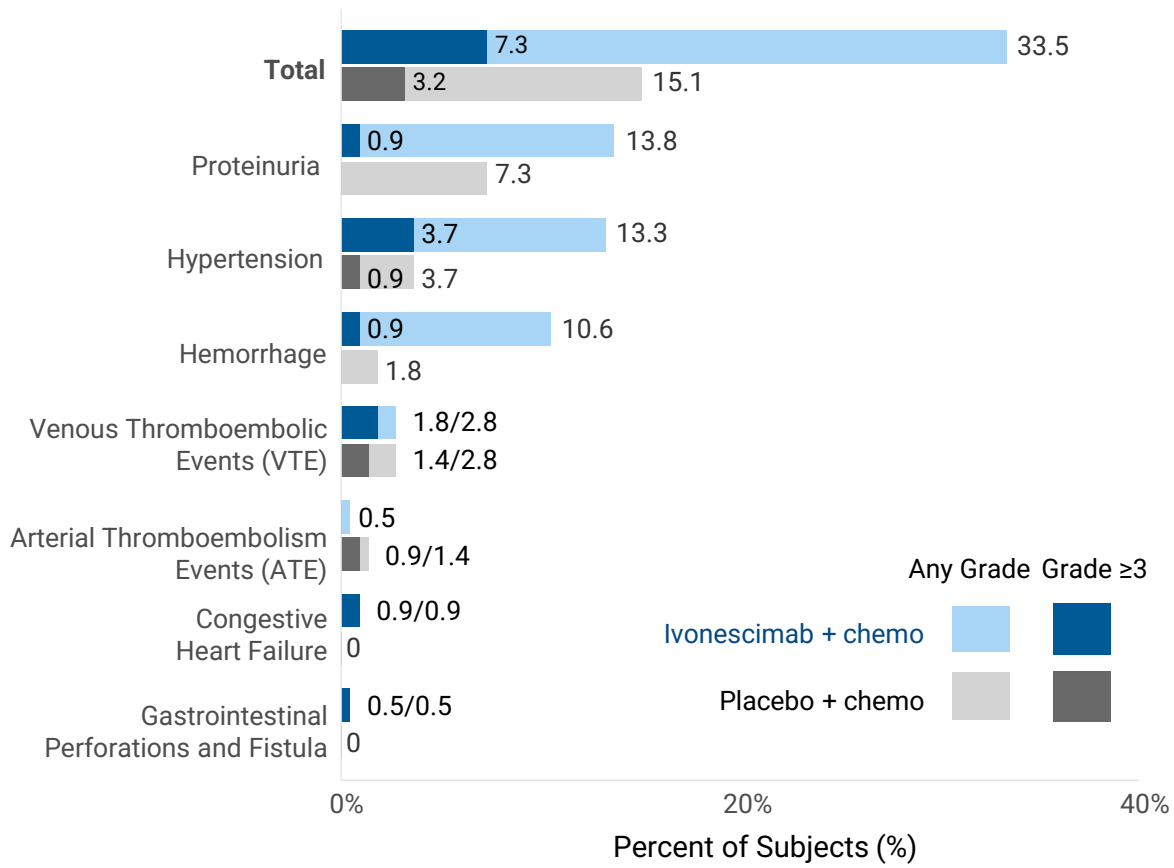
**Most common irAEs: hypo/hyperthryroidism, transaminase elevation, rash; mostly low grade**
**Most common VEGF-related TRAEs: proteinuria, hypertension, hemorrhage; mostly low grade**

## irAE



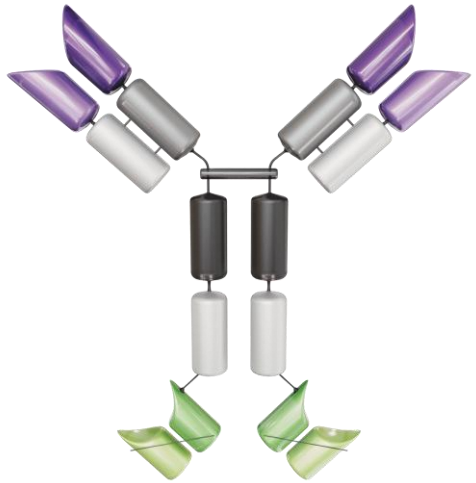

Pneumonitis/ILD, Ivo arm vs Pbo arm:
**2.8%** (1.4% Grade ≥3) vs **1.8%** (1.4% Grade ≥3)

## VEGF-related




d/c=discontinuation; ILD=interstitial lung disease; irAE=immune-related adverse events; ivo=ivonescimab; pbo=pembrolizumab; TRAE=treatment-related adverse events; VEGF= vascular endothelial growth factor.

# Summary



- Ivonescimab had a significant and clinically meaningful PFS benefit in EGFRm+ NSCLC patients post-3rd gen TKI
  - Reduced risk of progression or death by 48% vs chemotherapy, HR=0.52
  - Consistent efficacy across pre-defined subgroups
  - Increased ORR and DoR

- OS final analysis showed favorable trend; HR=0.79 with p=0.0570
  - Longer-term follow-up of Western patients showed stable OS; HR=0.78 with nominal p=0.0332
  - Western patients' median OS was numerically higher by 3 months

- Ivonescimab well tolerated, with no new safety findings
  - <1% Grade 3+ bleeding and comparable rates of discontinuation and death between arms

DoR=duration of response; EGFRm+=epidermal growth factor receptor mutation positive; EU=Europe; gen=generation; NA=North America; ORR=overall response rate; OS=overall survival; NSCLC=non-small cell lung cancer; TKI=tyrosine kinase inhibitor; PFS=progression-free survival.

# Acknowledgements

*Thank you to everyone who made this trial possible:*

- *The patients and their families*
- *The personnel at all the clinical study sites*
- *The scientists, regulatory, operations, and other teams within Summit and Akeso who helped develop ivonescimab and supported the study*

# Questions & Answers