

June 10, 2025

# Zepzelca<sup>®</sup> IMforte Data Webcast

**Innovating to Transform the Lives  
of Patients and Their Families**



# Transforming Lives. Redefining Possibilities.

## Caution Concerning Forward-Looking Statements

This presentation contains forward-looking statements and financial targets, including, but not limited to, statements related to: the Company's development, regulatory and commercialization strategy; the advancement of pipeline programs and the timing of development activities, regulatory activities and submissions related thereto; the Company's expectations with respect to its products and product candidates and the potential of the Company's products and product candidates, including the potential of zanidatamab to be more than a two billion dollar peak potential and to become the therapy of choice for multiple HER2+ tumors, the near-term commercialization potential of dordaviprone and the potential of Zepzelca plus atezolizumab to become the treatment of choice in 1L ES-SCLC in the maintenance setting; the Company's ability to realize the commercial potential of its products including the commercial plans with respect to Zepzelca in 1L ES-SCLC, if approved; potential regulatory approvals; and other statements that are not historical facts. These forward-looking statements are based on the Company's current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties.

Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: the successful completion of development and regulatory activities with respect to the Company's product candidates including Zepzelca in 1L-ESLC, zanidatamab in multiple HER2+ tumors and dordaviprone in recurrent H3 K27M-mutant diffuse glioma; obtaining and maintaining adequate coverage and reimbursement for the Company's products; the time-consuming and uncertain regulatory approval process, including the risk that the Company's current and/or planned regulatory submissions may not be submitted, accepted or approved by applicable regulatory authorities in a timely manner or at all, including the risk that the Company's supplemental new drug application for Zepzelca's use in combination with atezolizumab as maintenance therapy in 1L ES-SCLC for patients who have not progressed after induction chemotherapy and/or the Company's new drug application for dordaviprone for treatment of H3 K27M-mutant diffuse glioma in adult and pediatric patients with progressive disease following prior therapy may not be approved in a timely manner or at all, the costly and time-consuming pharmaceutical product development and the uncertainty of clinical success, including risks related to failure or delays in successfully initiating or completing clinical trials and assessing patients; global economic, financial, and healthcare system disruptions and the current and potential future negative impacts to the Company's business operations and financial results; protecting and enhancing the Company's intellectual property rights and the Company's commercial success being dependent upon the Company obtaining, maintaining and defending intellectual property protection and exclusivity for its products and product candidates; delays or problems in the supply or manufacture of the Company's products and product candidates; complying with applicable U.S. and non-U.S. regulatory requirements, including those governing the research, development, manufacturing and distribution; government investigations, legal proceedings and other actions; the sufficiency of the Company's cash flows and capital resources; and other risks and uncertainties affecting the Company, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals' Securities and Exchange Commission filings and reports, including the Company's Annual Report on Form 10-K for the year ended December 31, 2024 as supplemented by the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, and future filings and reports by the Company. Other risks and uncertainties of which the Company is not currently aware may also affect the Company's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated.



# Agenda



## Introduction and Overview

**Renée Galá**

President and Chief Operating Officer

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## Clinical Perspectives on Small-Cell Lung Cancer and Results from the IMforte Trial

**Stephen Liu, M.D.**

Medical Oncologist, Associate Professor of Medicine, Director of Thoracic Oncology at Georgetown University, Head of Developmental Therapeutics at Georgetown Lombardi Comprehensive Cancer Center

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## Zepzelca: Clinical and Development Overview

**Rob Iannone, M.D., M.S.C.E.**

Executive Vice President, Global Head of Research and Development and Chief Medical Officer

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## Zepzelca: Commercial Overview

**Sam Pearce**

Executive Vice President, Chief Commercial Officer



June 10, 2025

# Introduction and Overview

**Renée Galá**

**President and Chief Operating Officer**



# Highly Differentiated Medicines for Patients with Serious Diseases

Top-line growth driven by **diversified portfolio** of highly differentiated medicines

## Oncology

 **ZIIHERA**<sup>®</sup>  
(zanidatamab-hrii)

*Potential to be the therapy of choice in multiple HER2+ tumors*

 **ZEPZELCA**<sup>™</sup>  
(lurbinectedin)

*Leading treatment in 2L ES-SCLC; expansion opportunity in 1L ES-SCLC*

 **RYLAZE**<sup>®</sup>  
asparaginase erwinia chrysanthemi  
(recombinant)-rywn for injection 10mg/0.5mL per vial

*Standard of care in pediatric ALL/LBL patients with asparaginase HSR reaction*

## Neuroscience

 **Epidiolex**<sup>®</sup>

*#1 branded treatment for epilepsy<sup>1</sup>*

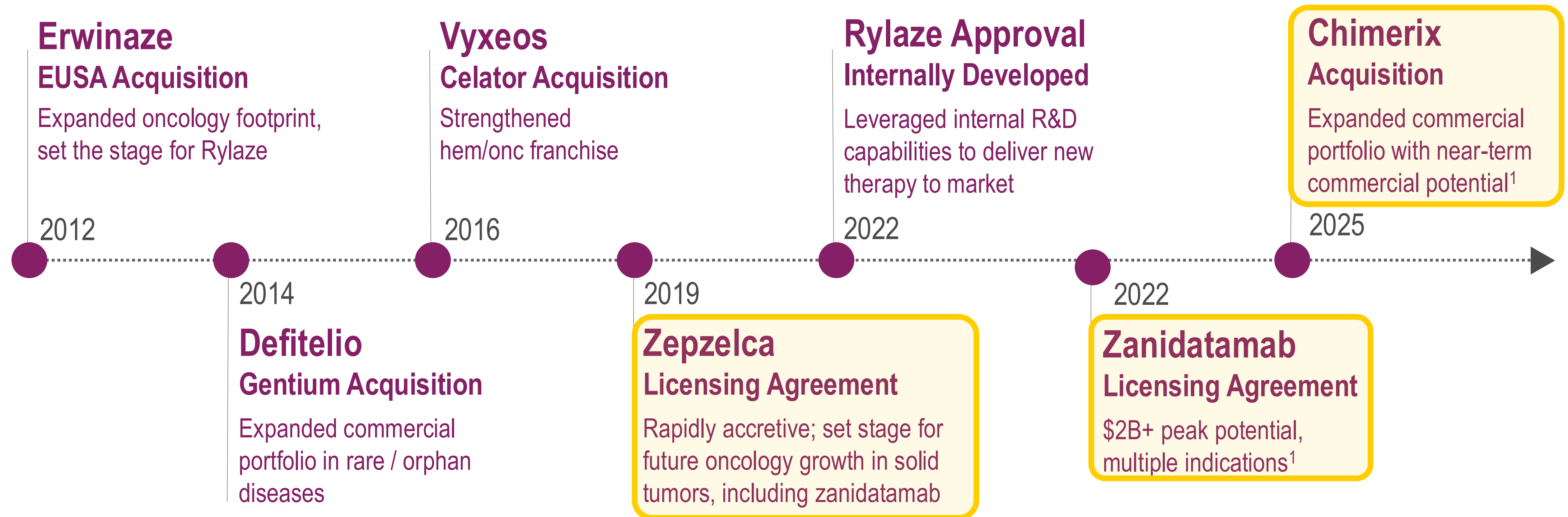
**xywav**<sup>™</sup> 


*#1 branded treatment for narcolepsy and only approved IH therapy<sup>1</sup>*

**Diverse product mix + strong cash flow generation**



# Evolution of Oncology Portfolio



 Denotes data presented in oral presentations at ASCO 2025

**Oncology transactions driving commercial growth and expanding R&D capabilities**



Note: Timeline shows select corporate development activity since 2012. Hem/onc = hematology & oncology. <sup>1</sup>Pending regulatory approval.

June 10, 2025

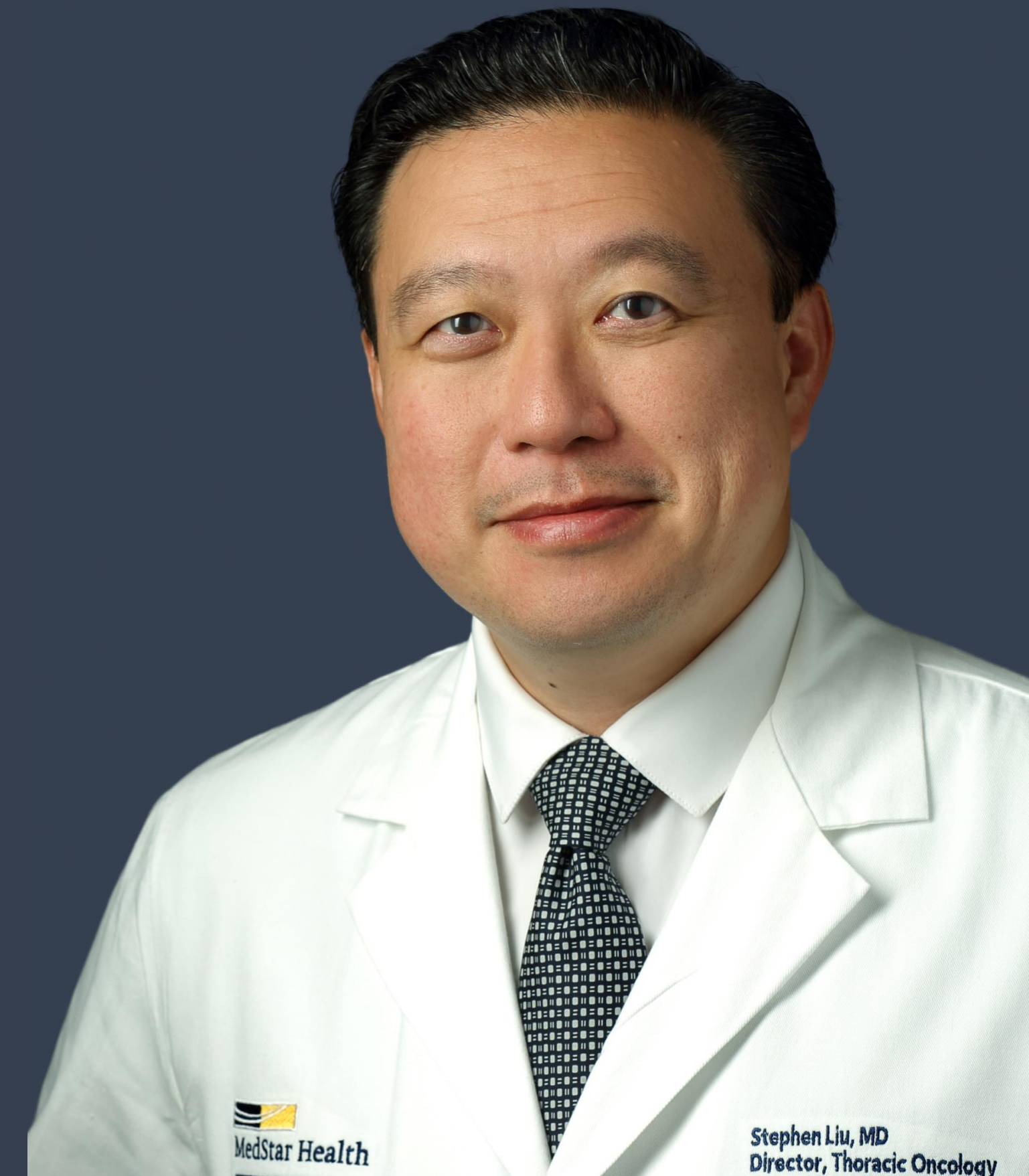
# IMforte Trial Results

**Stephen Liu, M.D.**

Medical Oncologist, Associate Professor of Medicine, Director of Thoracic Oncology at  
Georgetown University,  
Head of Developmental Therapeutics at Georgetown Lombardi Comprehensive Cancer Center



Dr. Stephen V. Liu, MD, is the Director of Thoracic Oncology and Head of Developmental Therapeutics at the Georgetown Lombardi Comprehensive Cancer Center. Dr. Liu is a board-certified medical oncologist. He leads the drug development program at Georgetown University and oversees thoracic oncology research at the cancer center. In addition to leading national and global clinical trials for the treatment of lung cancer, Dr. Liu is also the co-host for the official International Association for the Study of Lung Cancer, or IASLC, podcast, “Lung Cancer Considered.”



# Lurbinectedin + atezolizumab as first-line maintenance treatment in patients with extensive-stage small cell lung cancer: Primary results of the Phase 3 IMforte trial

Luis Paz-Ares,<sup>1</sup> Hossein Borghaei,<sup>2</sup> Stephen V. Liu,<sup>3</sup> Solange Peters,<sup>4</sup> Roy S. Herbst,<sup>5</sup> Katarzyna Stencel,<sup>6</sup> Margarita Majem,<sup>7</sup> Grzegorz Czyżewicz,<sup>8</sup> Reyes Bernabé Caro,<sup>9</sup> Ki Hyeong Lee,<sup>10</sup> Melissa L. Johnson,<sup>11</sup> Nuri Karadurmuş,<sup>12</sup> Christian Grohé,<sup>13</sup> Vaikunth Cuchelkar,<sup>14</sup> Vilma Graupner,<sup>15</sup> Monika Kaul,<sup>14</sup> Ya-Chen Lin,<sup>14</sup> Debasis Chakrabarti,<sup>16</sup> Kamalnayan Bhatt,<sup>16</sup> Martin Reck<sup>17</sup>

<sup>1</sup>Hospital Universitario 12 de Octubre, H12O-CNIO Lung Cancer Unit, Universidad Complutense and Ciberonc, Madrid, Spain; <sup>2</sup>Fox Chase Cancer Center, Philadelphia, PA, USA; <sup>3</sup>Lombardi Comprehensive Cancer Center, Georgetown University, Washington, DC, USA; <sup>4</sup>University Hospital CHUV, Lausanne, Switzerland; <sup>5</sup>Yale School of Medicine, New Haven, CT, USA; <sup>6</sup>Wielkopolska Center of Pulmonology and Thoracic Surgery of Eugenia and Janusz Zeyland, Poznan, Poland; <sup>7</sup>Hospital de la Santa Creu i Sant Pau, Barcelona, Spain; <sup>8</sup>The John Paul II Specialist Hospital, Kraków, Poland; <sup>9</sup>Hospital Universitario Virgen del Rocío, Seville, Spain; <sup>10</sup>Chungbuk National University Hospital, Cheongju, South Korea; <sup>11</sup>Tennessee Oncology, Sarah Cannon Research Institute, Nashville, TN, USA; <sup>12</sup>University of Health Sciences, Gülhane Training and Research Hospital, Ankara, Türkiye; <sup>13</sup>Klinik für Pneumologie, Evangelische Lungenklinik Berlin, Berlin, Germany; <sup>14</sup>Genentech Inc, South San Francisco, CA, USA; <sup>15</sup>F. Hoffmann-La Roche Ltd, Basel, Switzerland; <sup>16</sup>Jazz Pharmaceuticals plc, Dublin, Ireland; <sup>17</sup>Lung Clinic Grosshansdorf, Airway Research Center North, German Center of Lung Research, Grosshansdorf, Germany

# Key takeaway points

IMforte demonstrated a statistically significant and clinically meaningful improvement in PFS and OS with 1L maintenance treatment with lurbinectedin + atezolizumab vs atezolizumab in patients with ES-SCLC

The safety profile of the combination was predictable with an increased incidence of AEs, most of which were low grade; treatment discontinuation rates were low

The combination of lurbinectedin + atezolizumab has the potential to become the new standard of care for 1L maintenance treatment of ES-SCLC

# Background

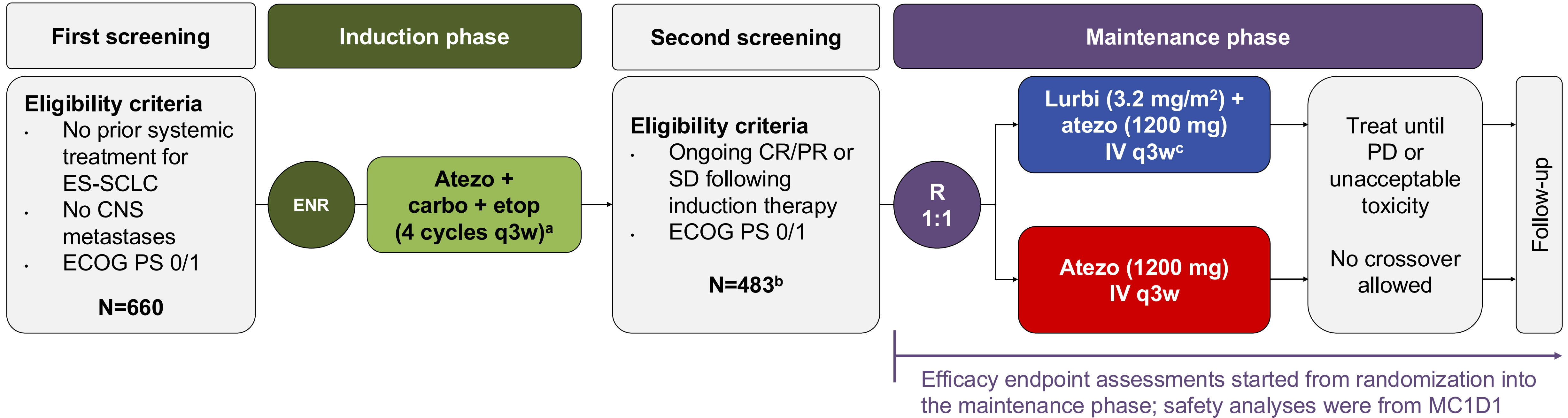
- Despite improved efficacy with 1L immune checkpoint inhibitors (ICIs) + platinum-based chemotherapy, most patients with ES-SCLC eventually experience disease progression and long-term survival remains limited<sup>1-5</sup>
- Due to the high attrition rate in ES-SCLC of ~60%<sup>6</sup>, offering the most effective treatment in the front-line setting before progression is crucial to improve outcomes in this difficult-to-treat disease
- Lurbinectedin is an alkylating agent and transcription inhibitor that is approved in the US and other countries for the treatment of patients with metastatic SCLC who experienced disease progression on or after platinum-based chemotherapy
- In pre-clinical studies, lurbinectedin was shown to synergize with ICIs<sup>7,8</sup> to achieve high rates of tumor regression and induce long-term T-cell memory<sup>9,10</sup>
- In Phase 1/2 trials in patients with relapsed ES-SCLC, the combination of lurbinectedin and ICIs was well tolerated with promising activity<sup>11-13</sup>

The global, open-label, randomized, Phase 3 IMforte study investigated the efficacy and safety of lurbinectedin + atezolizumab versus atezolizumab for the maintenance treatment of ES-SCLC in patients whose disease had not progressed after 1L induction treatment with atezolizumab + carboplatin + etoposide

1L, first line; ES-SCLC, extensive-stage small cell lung cancer; OS, overall survival; PFS, progression-free survival; SCLC, small cell lung cancer.

1. Liu SV, et al. J Clin Oncol 2021;39:619-30. 2. Paz-Ares L, et al. ESMO Open 2022;7:100408. 3. Goldman JW, et al. Lancet Oncol 2021;22:51-65. 4. Reck M, et al. Lung Cancer 2024;196:107924. 5. Cheng Y, et al. JAMA 2022;328:1223-32. 6. Ramirez RA, et al. ASCO 2022 [abstract 8584]. 7. Xie W, et al. Oncoimmunology 2019;8:e1656502. 8. Chakraborty S, et al. Cell Rep Med 2024;5:101852. 9. Russo-Cabrera JS, et al. Ann Oncol 2023;34:S636. 10. Russo-Cabrera JS, et al. AACR 2025 [abstract 5837]. 11. Calles A, et al. J Thorac Oncol 2025 doi: 10.1016/j.jtho.2025.02.005. 12. Ponce Aix S, et al. J Immunother Cancer 2021;9(Suppl 2):A493. 13. Ponce Aix S, et al. ASCO 2025 [abstract 8013].

# IMforte study design



## Stratification factors for randomization

- ECOG PS (0/1)
- LDH ( $\leq$ ULN/ $>$ ULN)
- Presence of liver metastases (Y/N) at induction BL
- Prior receipt of PCI (Y/N)

## Primary endpoints

IRF-PFS and OS

## Secondary endpoints included

INV-PFS, ORR, DOR, and safety

Last patient randomized: April 30, 2024

Clinical cutoff: July 29, 2024

ClinicalTrials.gov ID: NCT05091567.

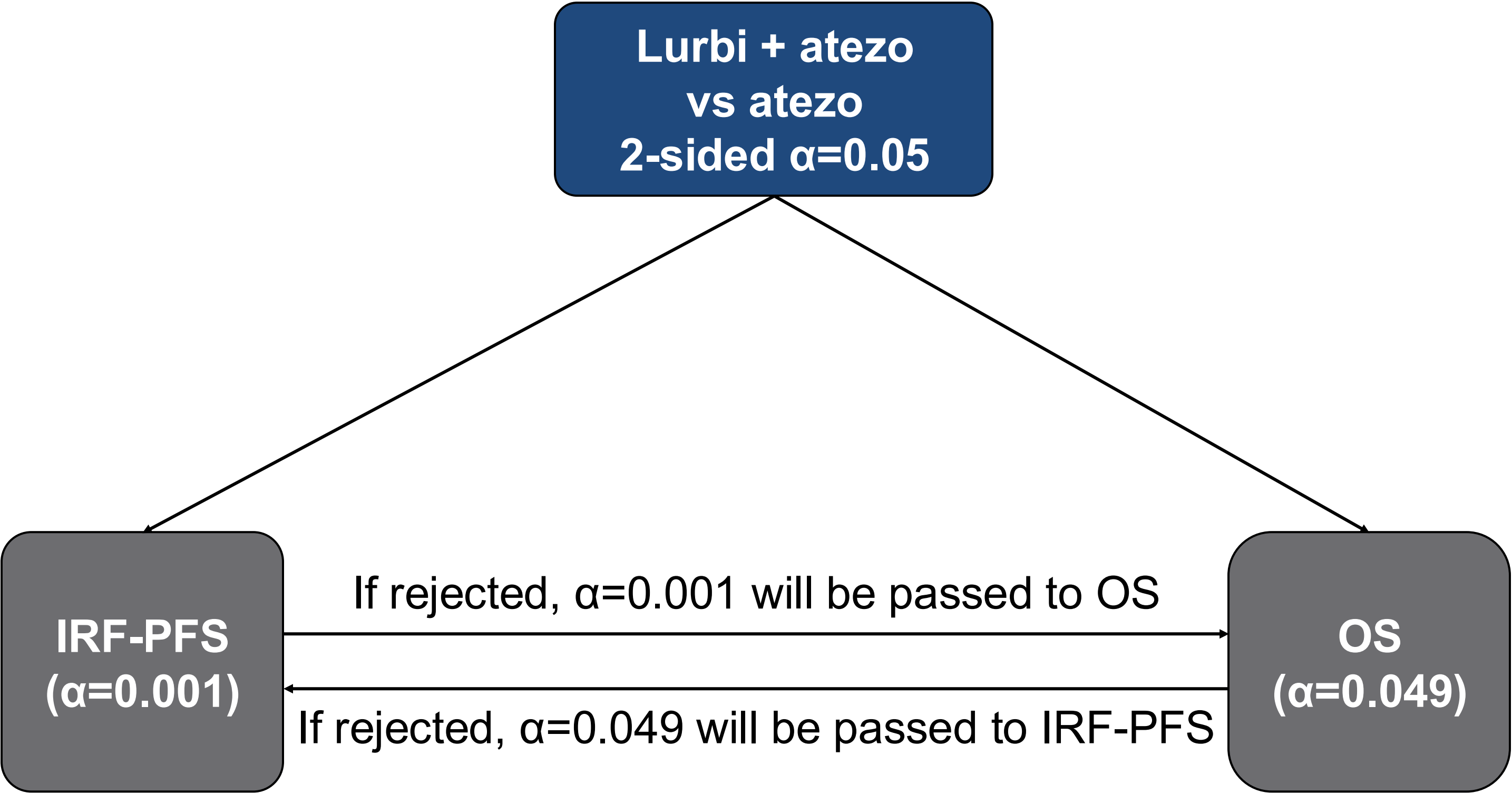
<sup>a</sup> Administered per standard dose. <sup>b</sup> 73% of patients continued from induction to maintenance. <sup>c</sup> With **prophylactic granulocyte colony-stimulating factor** and anti-emetics.

atezo, atezolizumab; BL, baseline; carbo, carboplatin; CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; ENR, enrollment; etop, etoposide; INV-PFS, investigator-assessed PFS; IRF-PFS, independent review facility-assessed PFS; IV, intravenously; LDH, lactate dehydrogenase; lurbi, lurbinectedin; MC1D1, maintenance Cycle 1 Day 1; PCI, prophylactic cranial irradiation; q3w, every 3 weeks; R, randomization; ULN, upper limit of normal; Y/N, yes/no.

# Statistical analysis plan

- OS
  - Target HR of 0.71 with a power of 85%
  - Interim analysis occurred when ~219 deaths were observed in the FAS<sup>a</sup> or when the minimum follow-up<sup>b</sup> was completed, whichever occurred later
  - If OS results were statistically significant at the interim analysis, they would constitute the primary analysis
- IRF-PFS
  - No interim analysis
  - Primary analysis was conducted at the time of OS interim analysis

## Type 1 error rate control strategy



<sup>a</sup> The FAS was defined as all patients randomized into the maintenance phase regardless of whether or not the assigned study treatment was received.

<sup>b</sup> The minimum follow-up was defined as 5 months after the target sample size of 450 participants had been randomized.

FAS, full analysis set.

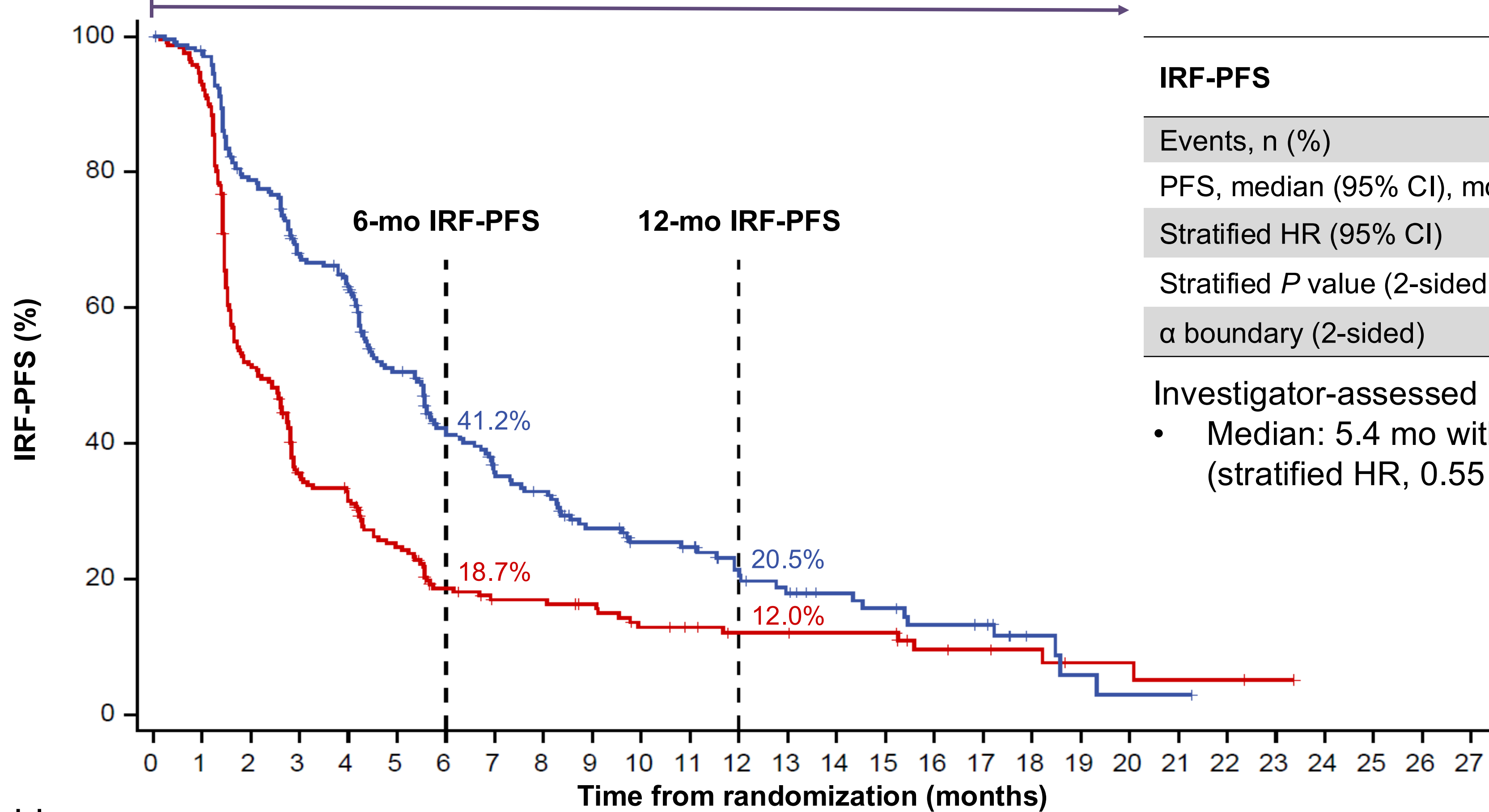
# Baseline characteristics of patients randomized into the maintenance phase

Characteristic	Lurbi + atezo (n=242)	Atezo (n=241)
<b>Age, median (range), years</b>	65.0 (38-85)	67.0 (35-85)
→ <b>&lt;65 years, n (%)</b>	118 (48.8)	90 (37.3)
<b>Sex, male, n (%)</b>	151 (62.4)	151 (62.7)
<b>Race, n (%)</b>		
White	195 (80.6)	199 (82.6)
Asian	31 (12.8)	31 (12.9)
Other <sup>a</sup>	16 (6.6)	11 (4.6)
<b>Current or previous tobacco use history, n (%)</b>	235 (97.1)	236 (97.9)
→ <b>Liver metastases at induction BL, n (%)<sup>b</sup></b>	100 (41.3)	94 (39.0)
<b>Prior PCI, n (%)<sup>b</sup></b>	34 (14.0)	37 (15.4)
<b>ECOG PS 0 at maintenance BL, n (%)<sup>b</sup></b>	105 (43.4)	102 (42.3)
<b>LDH ≤ULN at maintenance BL, n (%)<sup>b</sup></b>	176 (72.7)	179 (74.3)
→ <b>Time from induction Cycle 1 Day 1 to randomization, median (range), mo</b>	3.2 (2.6-4.6)	3.2 (2.7-5.2)
<b>Response to induction therapy, n (%)<sup>c</sup></b>		
→ CR/PR	206 (87.3)	213 (88.8)
SD	28 (11.9)	25 (10.4)
PD <sup>d</sup>	2 (0.8)	2 (0.8)

Clinical cutoff: July 29, 2024. <sup>a</sup> Includes American Indian or Alaska Native and Black or African American patients, as well as patients with unreported race. <sup>b</sup> Stratification factors for randomization; data determined from electronic case-report forms. <sup>c</sup> n=236 in the lurbi + atezo arm and n=240 in the atezo arm; 7 randomized patients did not have a maintenance screening tumor assessment. <sup>d</sup> Randomization of these patients was in violation of the protocol. BL, baseline. PCI, prophylactic cranial irradiation.

# IRF-PFS from randomization into maintenance phase

**R** PFS assessment started from randomization into the maintenance phase



IRF-PFS	Lurbi + atezo (n=242)	Atezo (n=241)
Events, n (%)	174 (71.9)	202 (83.8)
PFS, median (95% CI), mo	5.4 (4.2, 5.8)	2.1 (1.6, 2.7)
Stratified HR (95% CI)	<b>0.54 (0.43, 0.67)</b>	
Stratified P value (2-sided)	<0.0001	
α boundary (2-sided)	0.001	

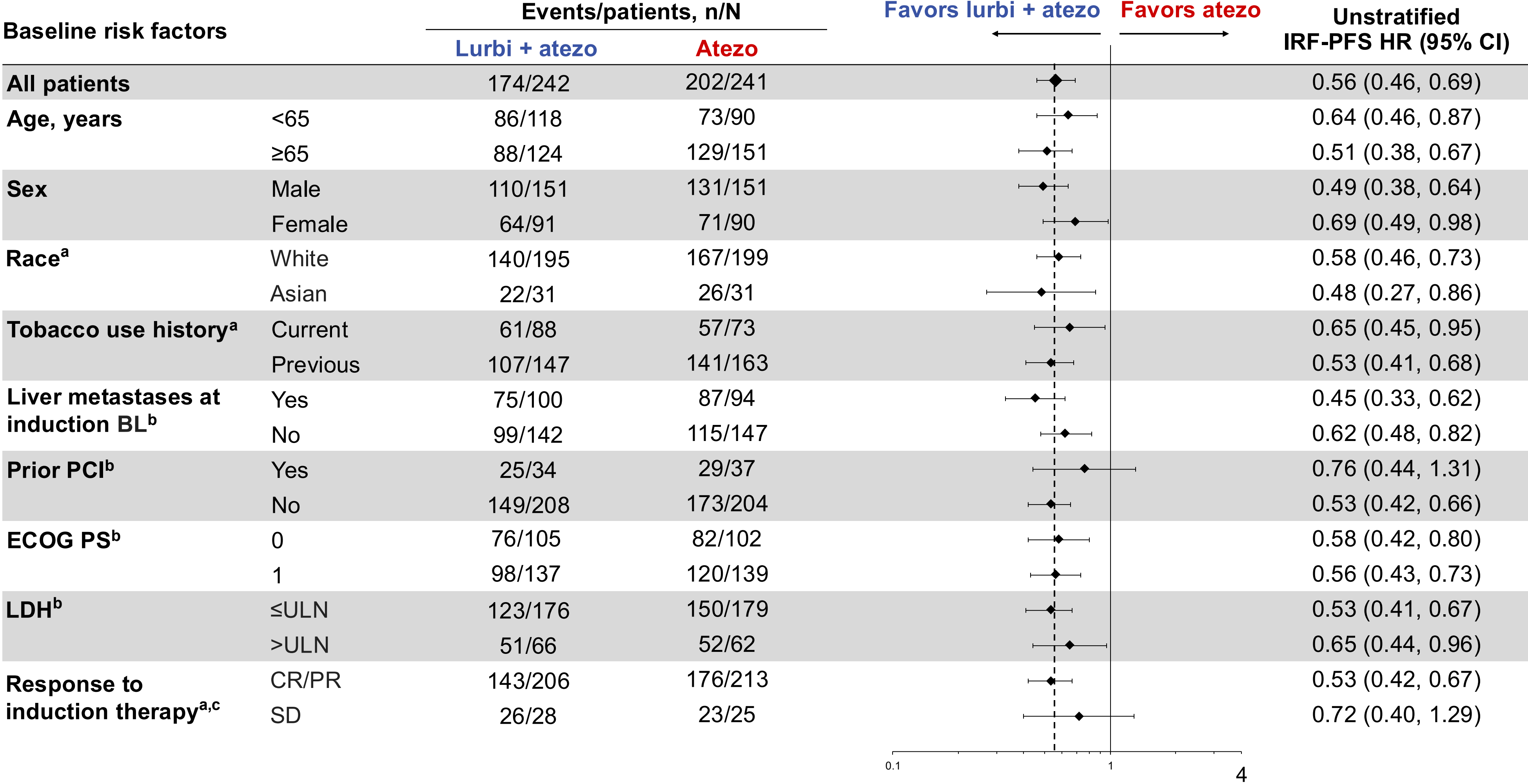
Investigator-assessed PFS was consistent with IRF-PFS

- Median: 5.4 mo with lurbi + atezo and 2.7 mo with atezo (stratified HR, 0.55 [95% CI: 0.45, 0.68])

No. at risk	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
Lurbi + atezo	242	231	184	152	138	103	76	62	57	43	35	33	24	20	16	14	11	10	4	2	1	1	0	0	0	0	0	0
Atezo	241	224	123	79	69	50	34	27	27	24	18	16	13	13	12	12	7	6	5	3	3	2	2	1	0	0	0	0

Clinical cutoff: July 29, 2024; median survival follow-up: 15.0 mo (minimum follow-up: 3.0 mo).  
 CI, confidence interval; HR, hazard ratio.

# IRF-PFS subgroup analysis

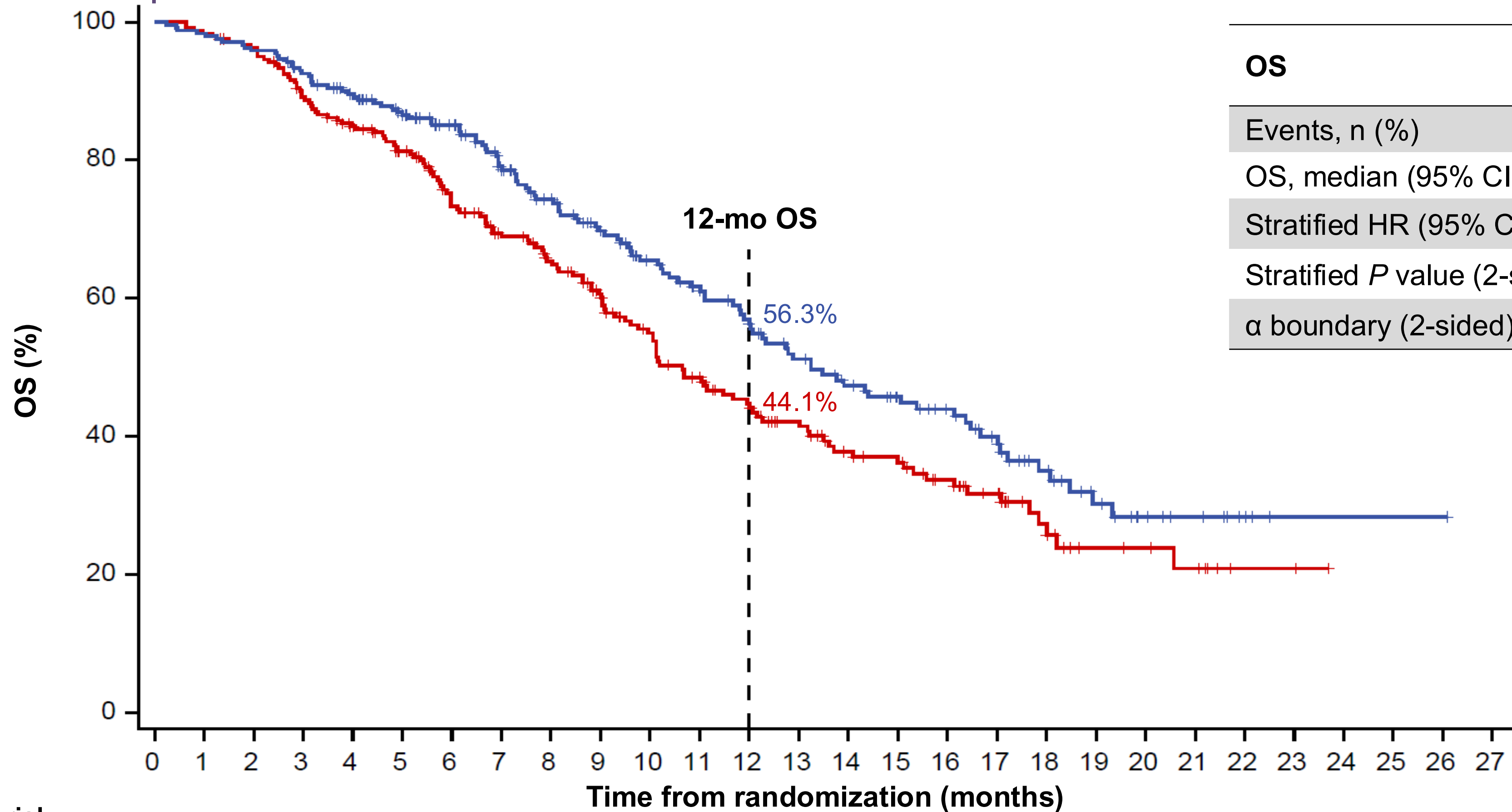


Clinical cutoff: July 29, 2024; median survival follow-up: 15.0 mo (minimum follow-up: 3.0 mo).

<sup>a</sup> Data from subgroups with small numbers are not displayed. <sup>b</sup> Stratification factor for randomization; data determined from electronic case-report forms. <sup>c</sup> n=236 in the lurbi + atezo arm and n=240 in the atezo arm; 7 randomized patients did not have a maintenance screening tumor assessment.

# OS from randomization into maintenance phase

**R** OS assessment started from randomization into the maintenance phase  
 (median time from induction C1D1 to randomization: 3.2 months in each arm)

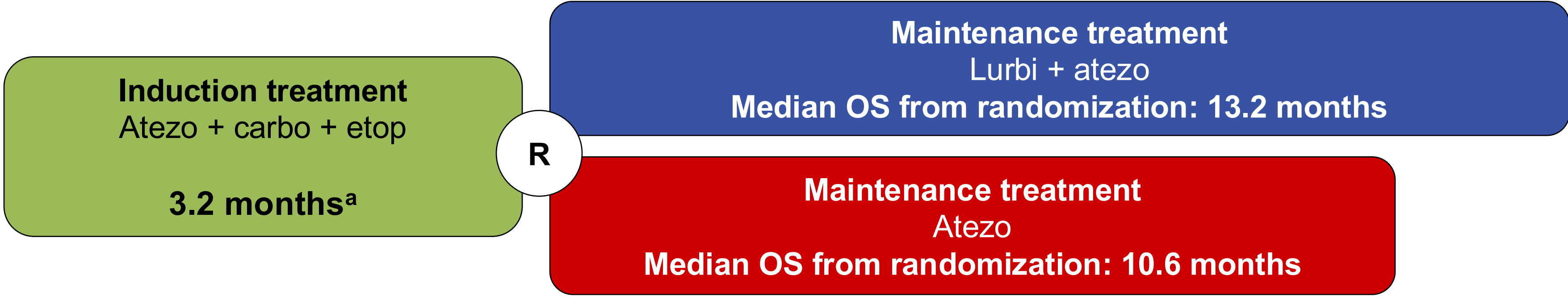
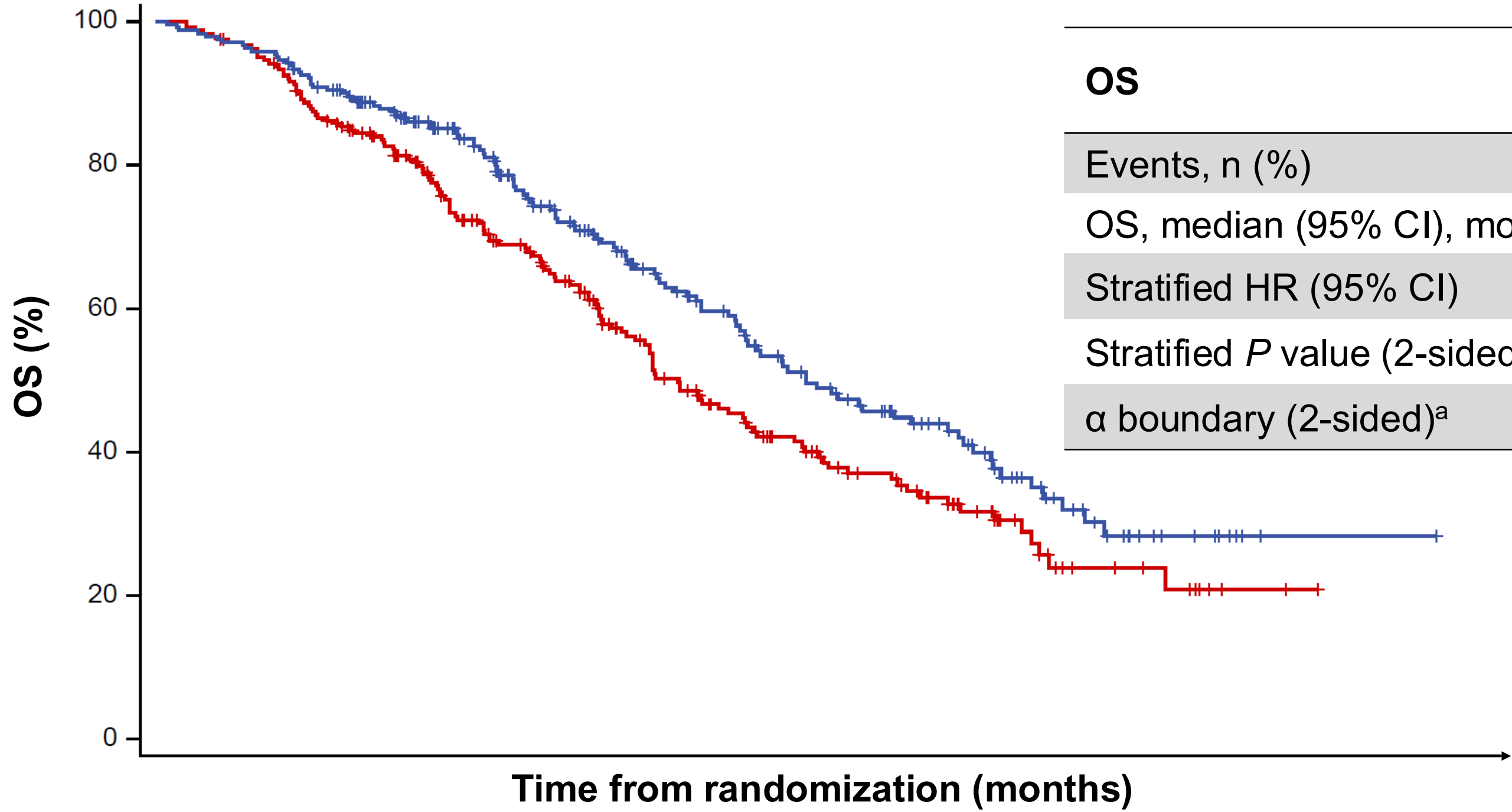


OS	Lurbi + atezo (n=242)	Atezo (n=241)
Events, n (%)	113 (46.7)	136 (56.4)
OS, median (95% CI), mo	13.2 (11.9, 16.4)	10.6 (9.5, 12.2)
Stratified HR (95% CI)	<b>0.73 (0.57, 0.95)</b>	
Stratified P value (2-sided)	0.0174	
α boundary (2-sided) <sup>a</sup>	0.0313	

No. at risk	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
Lurbi + atezo	242	238	232	221	209	191	174	151	136	118	104	93	81	69	60	52	46	36	25	17	11	8	4	1	1	1	1	0
Atezo	241	237	230	211	196	179	154	138	126	111	94	81	69	60	49	45	37	29	17	10	9	7	2	2	0	0	0	0

Clinical cutoff: July 29, 2024; median survival follow-up: 15.0 mo (minimum follow-up: 3.0 mo).  
<sup>a</sup> As determined by the Hwang-Shih-Decani alpha spending function with the gamma parameter of -1.5.

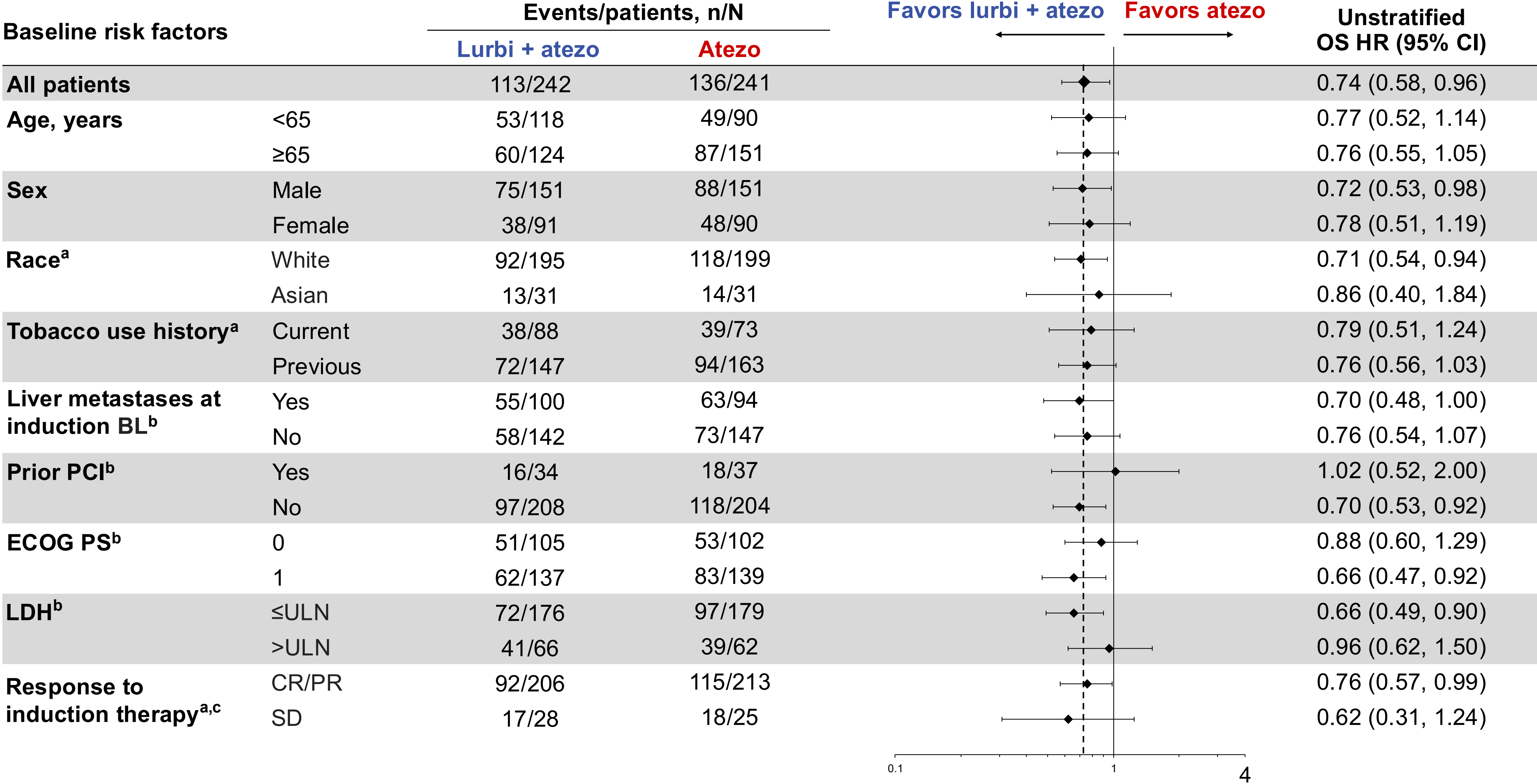
# OS from randomization into maintenance phase



**IMforte results do not include time on induction treatment**

<sup>a</sup> Median time from start of induction treatment to randomization was analyzed for 483 randomized patients. Note: 660 patients were enrolled into the induction phase, out of whom 177 patients were not randomized into the maintenance phase.

# OS subgroup analysis



Clinical cutoff: July 29, 2024; median survival follow-up: 15.0 mo (minimum follow-up: 3.0 mo).

<sup>a</sup> Data from subgroups with small numbers are not displayed. <sup>b</sup> Stratification factor for randomization; data determined from electronic case-report forms. <sup>c</sup> n=236 in the lurbi + atezo arm and n=240 in the atezo arm; 7 randomized patients did not have a maintenance screening tumor assessment.

# Confirmed IRF-assessed ORR and DOR during the maintenance phase

- Background: At the time of randomization, 88% of patients had CR/PR and 11% had SD to induction therapy
  - Tumor response in the maintenance phase was assessed against maintenance baseline

Patients with measurable disease <sup>a</sup>	Lurbi + atezo (n=175)	Atezo (n=182)
<b>Confirmed objective response, n (%) (95% CI)<sup>b</sup></b>	34 (19.4) (13.9, 26.1)	19 (10.4) (6.4, 15.8)
Difference in ORR (95% CI), %	9.0 (1.1, 16.9)	
CR, n (%)	4 (2.3)	1 (0.5)
PR, n (%)	30 (17.1)	18 (9.9)
SD, n (%)	96 (54.9)	68 (37.4)
PD, n (%)	34 (19.4)	87 (47.8)
Missing or non-evaluable, n (%)	11 (6.3)	8 (4.4)
<b>DOR<sup>c</sup></b>		
Responders with an event/responders, n (%)	14/34 (41.2)	11/19 (57.9)
Median DOR (95% CI), mo	9.0 (5.5, NE)	5.6 (4.2, NE)

Clinical cutoff: July 29, 2024. <sup>a</sup> Measurable disease was not an inclusion criterion to enter the maintenance phase. <sup>b</sup> The confirmed ORR was defined as the proportion of randomized patients with a CR or PR on two consecutive occasions  $\geq 4$  weeks apart after randomization and was assessed in patients who had measurable disease at maintenance baseline. <sup>c</sup> DOR was assessed in patients who had a confirmed objective response in the maintenance phase. NE, not estimable.

# Follow-up systemic anticancer treatments

Patients, n (%)	Lurbi + atezo (n=242)	Atezo (n=241)
Patients who discontinued maintenance treatment	197	208
Patients with ≥1 follow-up systemic anticancer treatment	108 (44.6)	132 (54.8)
Chemotherapy	89 (36.8)	119 (49.4)
Immunotherapy	25 (10.3)	20 (8.3)
Targeted therapy	3 (1.2)	2 (0.8)
Other	3 (1.2)	3 (1.2)

At the time of clinical cutoff, no patient in the lurbi + atezo arm and 22 patients (9.1%) in the atezo arm had received follow-up lurbi treatment

Clinical cutoff: July 29, 2024.

# Safety summary during the maintenance phase

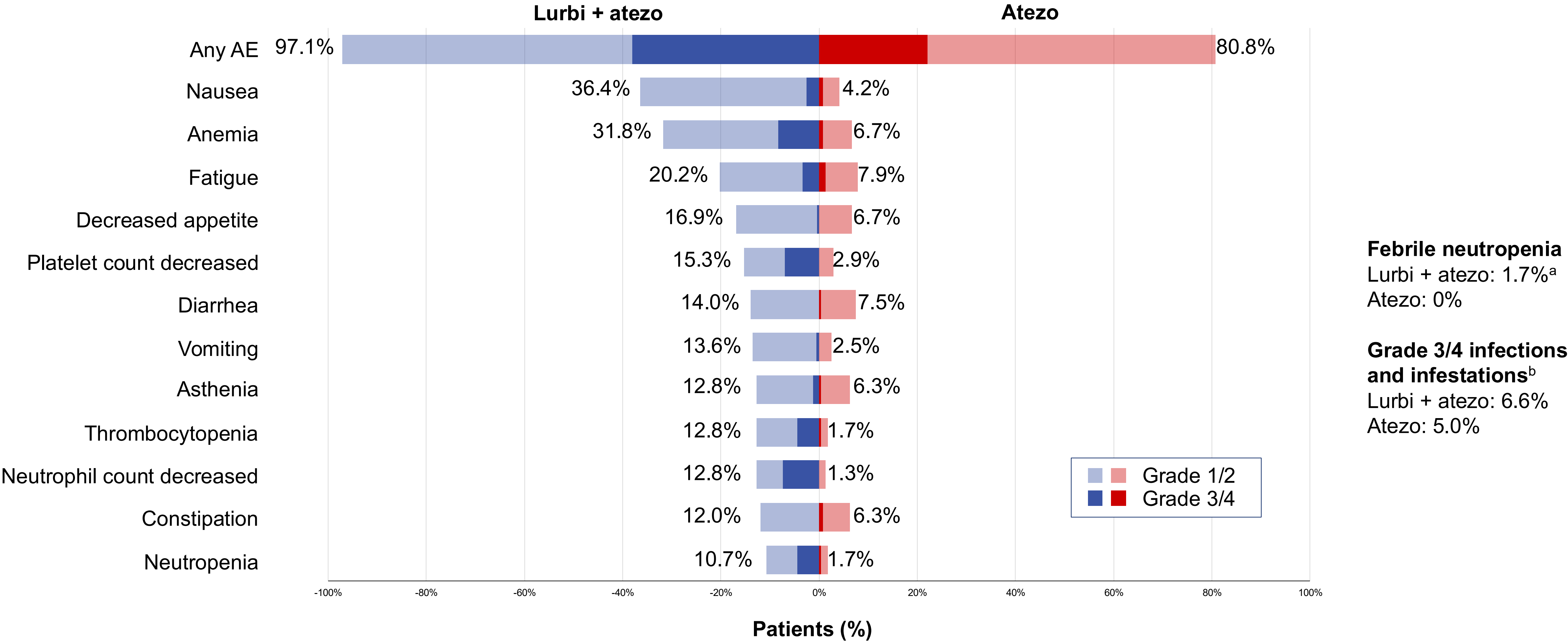
Patients with ≥1 AE, n (%)	Lurbi + atezo (n=242)	Atezo (n=240)
All-cause AEs	235 (97.1)	194 (80.8)
Grade 3/4 AEs	92 (38.0)	53 (22.1)
Treatment-related Grade 3/4 AEs	62 (25.6)	14.0 (5.8)
Grade 5 AEs	12 (5.0)	6 (2.5)
Treatment-related Grade 5 AEs	2 (0.8) <sup>a</sup>	1 (0.4) <sup>b</sup>
Serious AEs	75 (31.0)	41 (17.1)
AEs leading to discontinuation of any study drug	15 (6.2)	8 (3.3)
AEs leading to dose interruption/ modification of any study drug <sup>c</sup>	92 (38.0)	33 (13.8)

Patients with ≥1 AE, n (%)	Lurbi + atezo (n=242)	Atezo (n=240)
Lurbinectedin AESI <sup>d</sup>	93 (38.4)	62 (25.8)
Grade 5 AESI	7 (2.9)	4 (1.7)
Atezolizumab AESI <sup>d</sup>	76 (31.4)	54 (22.5)
Grade 5 AESI	0	0
Atezolizumab AESI requiring corticosteroids	40 (16.5)	18 (7.5)
Median treatment duration, mo	4.1 (lurbi)/ 4.2 (atezo)	2.1
Median number of doses received	6.5 (lurbi)/ 7.0 (atezo)	4.0

Clinical cutoff: July 29, 2024. One patient randomized to the atezo arm did not receive treatment and was not included in the safety analysis set.

<sup>a</sup> Sepsis and febrile neutropenia, both considered related to lurbi. <sup>b</sup> Sepsis considered related to atezo. <sup>c</sup> Atezo dose modifications were not permitted. <sup>d</sup> AESI for lurbi and atezo were pre-specified based on their mechanism of action and were independent of the causal relationship assigned by the investigator. AE, adverse event; AESI, adverse events of special interest.

# All-cause AEs with incidence $\geq 10\%$ in either arm



Clinical cutoff: July 29, 2024. Percentage labels represent all-grade AEs, including Grade 5 AEs. Grade 5 AEs occurred in 12 (5.0%) patients in the lurbi + atezo arm and 6 (2.5%) patients in the atezo arm.  
<sup>a</sup> Includes 1 Grade 5 AE. <sup>b</sup> Grade 5 infections: lurbi + atezo arm (n=6 [2.5%]): COVID-19 pneumonia, pneumonia, pneumonia viral, sepsis, septic shock, and vascular device infection (n=1 each); atezo arm (n=4 [1.7%]): pneumonia (n=2), abscess intestinal, and sepsis (n=1 each).

# Conclusions

- IMforte demonstrated a statistically significant and clinically meaningful improvement in IRF-PFS and OS with 1L maintenance treatment with lurbinectedin + atezolizumab vs atezolizumab in patients with ES-SCLC
  - Stratified IRF-PFS HR: 0.54 (95% CI: 0.43, 0.67);  $P < 0.0001$
  - Stratified OS HR: 0.73 (95% CI: 0.57, 0.95);  $P = 0.0174$
- IRF-PFS and OS benefit with lurbinectedin + atezolizumab was generally consistent across the majority of subgroups
- Despite the higher rate of Grade 3/4 AEs and SAEs, there were no new or unexpected safety signals with lurbinectedin + atezolizumab
  - The safety profile was predictable, with mostly low-grade AEs and low treatment discontinuation rates
  - There was no clinically meaningful increase in immune-related AEs
- IMforte is the first Phase 3 study to show PFS and OS improvement with 1L maintenance treatment for ES-SCLC, highlighting the potential of lurbinectedin + atezolizumab to become a new standard of care for 1L maintenance therapy in patients with this aggressive and difficult-to-treat disease

June 10, 2025

# Clinical and Development Overview

**Rob Iannone, M.D., M.S.C.E.**

**Executive Vice President,  
Global Head of Research and Development and  
Chief Medical Officer**



# IMforte Data Brings Meaningful Improvement to 1L ES-SCLC Patients

**Outcomes in first-line treatments of ES-SCLC need improvement<sup>1-8</sup>**

**MoA of lurbinectedin and preclinical evidence support the combination of lurbinectedin and ICIs<sup>9-13</sup>**

**Combining atezolizumab with lurbinectedin in maintenance is supported by substantial evidence of efficacy and safety of the individual agents in 1L and 2L settings<sup>14-17</sup>**

**Adding lurbinectedin to atezolizumab in the maintenance phase demonstrated improved outcomes for patients with ES-SCLC<sup>17</sup>**



# IMforte Data Represents Potential to Shift 1L ES-SCLC Treatment Paradigm

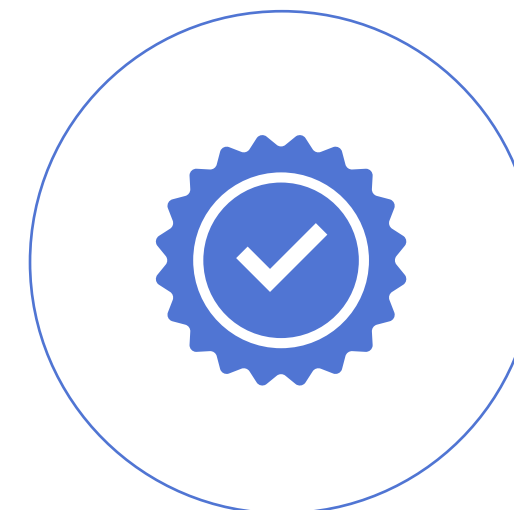
## IMforte data presented at ASCO



## Simultaneous publication in *The Lancet*



## sNDA granted Priority Review with October 7, 2025, PDUFA target date



## IMforte data submitted to NCCN



June 10, 2025

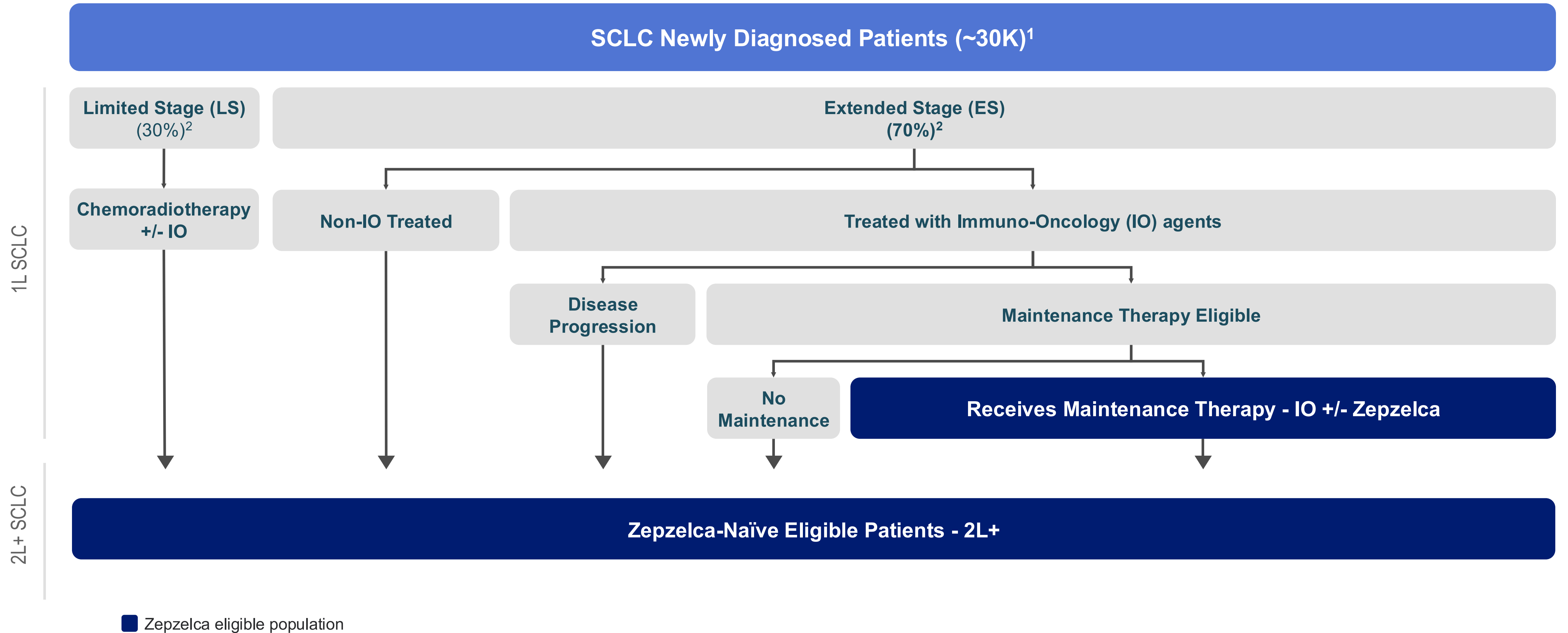
# Commercial Overview

**Samantha Pearce**

**Executive Vice President, Chief Commercial Officer**



# First-Line Use Drives Zepzelca Growth Opportunity



# IMforte Data Support Use of Zepzelca as a Foundational SCLC Treatment

1

## Drive Further Adoption of 1L Maintenance Regimen

- Educate prescribers and patients on the benefits of receiving maintenance therapy, which can result in prolonged survival
- Maintenance options, including Zepzelca combination, are well tolerated

2

## Establish Zepzelca as 1L Treatment of Choice in Maintenance Setting<sup>1</sup>

- Practice-changing data from combination of Zepzelca + atezolizumab improved survival outcomes for patients with 1L ES-SCLC
- Zepzelca + atezolizumab showed a manageable safety profile in patients

3

## Continued Use in 2L+ Zepzelca-Naïve Patients

- Limited-stage patients remain eligible for treatment with Zepzelca once progression occurs
- Important treatment option for Zepzelca-naïve patients in later lines of therapy



# Thank You

