ASTRUM-005

Randomized, Double-Blind, Multicenter, Phase 3 Study

Serplulimab is not approved for use in the United States (US). Results shown here are from the international clinical trial. Clinical investigation of serplulimab in the US is underway.

FOSUN PHARMA USA INC.

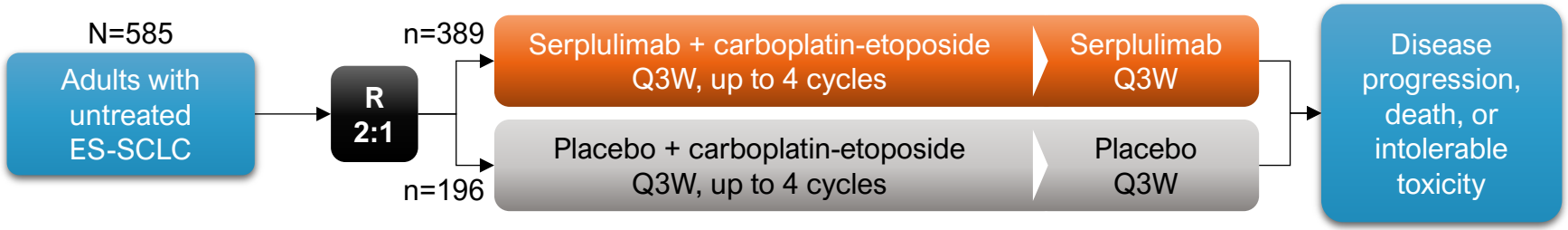
SER-MED-001-v2.0-08/2024

ASTRUM-005: International, Randomized, Double-Blind, Multicenter, Phase 3 Study of Serplulimab vs Placebo Added to Chemotherapy in Previously Untreated Patients With ES-SCLC

FOSUN PHARMA USA INC.

Serplulimab is not approved for use in the United States (US). Results shown here are from the international clinical trial. Clinical investigation of serplulimab in the US is underway.

Study design: Phase 3, double-blind, placebo-controlled, randomized study[1]



Key endpoints[1]

Primary: OS

Secondary: PFS, ORR, DOR, QoL, PK, correlative biomarker analyses

Safety: AEs

Key inclusion criteria[2]

- Aged ≥18 years
- Histologically or cytologically diagnosed with ES-SCLC
- ≥1 measurable lesion
- Stable and treated brain metastases
- ECOG PS 0 or 1
- No significant organ dysfunction
- Expected survival ≥12 weeks

Key exclusion criteria[2]

- Histologically or cytologically confirmed mixed-stage SCLC
- Prior systemic SCLC treatments
- Grade ≥2 peripheral neuropathy
- Ejection fraction <50% or NYHA class III to IV cardiac insufficiency
- Pregnant or breastfeeding females

Study sites[1]

Clinical trial was conducted in China, Georgia, Poland, Russia, Turkey, and Ukraine

All patients received 100 mg/m^2 of etoposide on Days 1, 2, and 3 and carboplatin within the area under the serum drug concentration time curve of 5 mg/mL/min (up to 750 mg) on Day 1 of each cycle for up to 4 cycles via intravenous infusions. Patients were eligible to continue receiving the assigned treatment after disease progression at the discretion of the investigators if prespecified criteria were met.[1]

AE=adverse event; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group performance status; ES-SCLC=extensive-stage small cell lung cancer; NYHA=New York Heart Association; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; PK=pharmacokinetic; Q3W=every 3 weeks; QoL=quality of life; R=randomization; SCLC=small cell lung cancer.

1. Cheng Y, et al. *JAMA*. 2022;328(12):1223-1232. 2. Cheng Y, et al. *JAMA*. 2022;328(12):1223-1232 [Supplemental Appendix 2].

Phase 3 ASTRUM-005 Study

Overall Survival

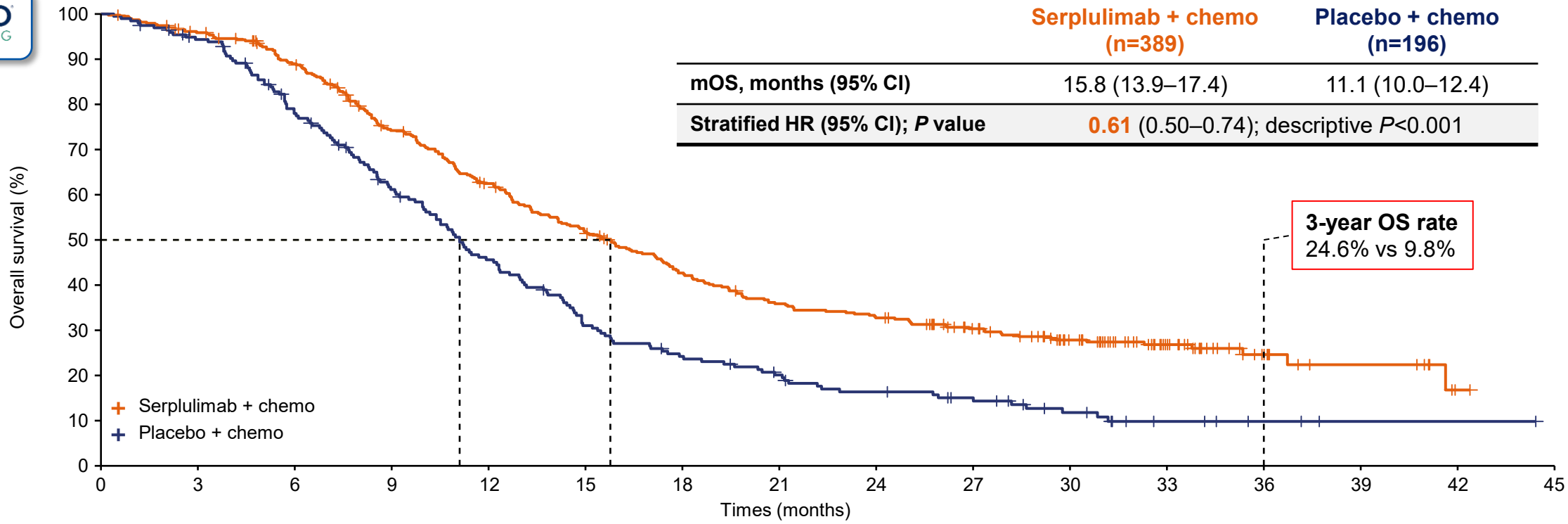
Median Follow-up: 31.6 Months

Serplulimab is not approved for use in the United States (US). Results shown here are from the international clinical trial. Clinical investigation of serplulimab in the US is underway.

2024 ASCO ANNUAL MEETING

FOSUN PHARMA USA INC.

	Serplulimab + chemo (n=389)	Placebo + chemo (n=196)
mOS, months (95% CI)	15.8 (13.9–17.4)	11.1 (10.0–12.4)
Stratified HR (95% CI); *P* value	**0.61** (0.50–0.74); descriptive *P*<0.001	



Number at risk

Serplulimab + chemo	389	368	335	273	227	187	151	126	115	91	67	38	15	8	1	0
Placebo + chemo	196	181	146	111	82	55	42	33	26	21	13	6	3	1	1	0

Chemo=chemotherapy (etoposide + carboplatin); CI=confidence interval; HR=hazard ratio; mOS=median overall survival; OS=overall survival.

Cheng Y, et al; ASTRUM-005 Study Group. Serplulimab vs. placebo combined with chemotherapy as first-line treatment for extensive-stage small-cell lung cancer: extended follow-up results and patient-reported outcomes from the international phase 3 ASTRUM-005 study. Presented at: ASCO Annual Meeting; May 31-June 4, 2024; Chicago, IL.

Phase 3 ASTRUM-005 Study

Overall Survival in Non-Asian (Eastern European Caucasian) Population

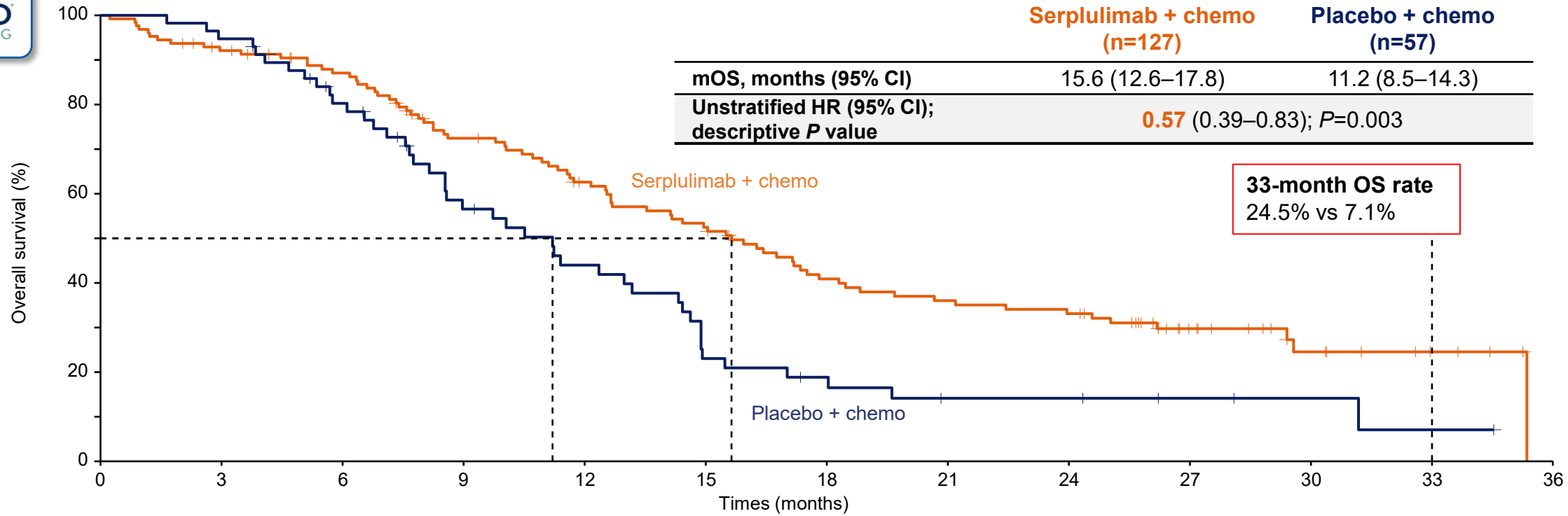
Median Follow-up: 31.6 Months

Serplulimab is not approved for use in the United States (US). Results shown here are from the international clinical trial. Clinical investigation of serplulimab in the US is underway.

2024 ASCO ANNUAL MEETING

FOSUN PHARMA USA INC.

	Serplulimab + chemo (n=127)	Placebo + chemo (n=57)
mOS, months (95% CI)	15.6 (12.6–17.8)	11.2 (8.5–14.3)
Unstratified HR (95% CI); descriptive *P* value	**0.57** (0.39–0.83); *P*=0.003	



Number at risk

+	127	114	103	82	68	57	42	37	34	18	9	4	0
+	57	54	43	28	21	11	8	5	5	3	2	1	0

Chemo=chemotherapy (etoposide + carboplatin); CI=confidence interval; HR=hazard ratio; mOS=median overall survival; OS=overall survival.

Cheng Y, et al; ASTRUM-005 Study Group. Serplulimab vs. placebo combined with chemotherapy as first-line treatment for extensive-stage small-cell lung cancer: extended follow-up results and patient-reported outcomes from the international phase 3 ASTRUM-005 study. Presented at: ASCO Annual Meeting; May 31-June 4, 2024; Chicago, IL.

Phase 3 ASTRUM-005 Study

Safety Profile

Serplulimab is not approved for use in the United States (US). Results shown here are from the international clinical trial. Clinical investigation of serplulimab in the US is underway.

	Serplulimab + chemo (n=389)	Placebo + chemo (n=196)
TEAEs,[1] n (%)	373 (95.9)	191 (97.4)
CTCAE Grade ≥3	324 (83.3)	160 (81.6)
SAEs	146 (37.5)	71 (36.2)
AESIs		
IRRs	7 (1.8)	1 (0.5)
irAEs	147 (37.8)	38 (19.4)
Treatment-related TEAEs,[1] n (%)	273 (70.2)	113 (57.7)
CTCAE Grade ≥3	133 (34.2)	57 (29.1)
Leading to treatment D/C	23 (5.9)	10 (5.1)
Leading to death	5 (1.3)	1 (0.5)

Incidence of TEAEs,[2] %

	Grade 1-2*		Grade 3-5*	
	Serplulimab + chemo (n=389)	Placebo + chemo (n=196)	Serplulimab + chemo (n=389)	Placebo + chemo (n=196)
Anemia	52.4	52.5	19.3	18.4
Alopecia	54.2	56.1	0	0.5
Neutrophil count decreased	13.6	11.2	42.7	40.3
WBC count decreased	29.5	26	24.2	25
Platelet count decreased	25.2	25.5	15.9	19.4
Nausea	35.2	42.9	1	1
Neutropenia	6.7	10.7	22.9	20.9
Decreased appetite	27.2	28.1	0.8	0.5
Constipation	24.2	29.6	0	0
Vomiting	19	28.6	1.3	1
Leukopenia	14.9	9.7	9.5	11.2
Hyponatremia	14.9	7.2	9.8	6.1

*Grade 1-5 adverse events/treatment-related adverse events are categorized as mild (Grade 1), moderate (Grade 2), severe (Grade 3), potentially life-threatening (Grade 4), or death (Grade 5).[2]

AESI=adverse event of special interest; chemo=chemotherapy (etoposide + carboplatin); CTCAE=Common Terminology Criteria for Adverse Events; D/C=discontinuation; irAE=immune-related adverse event; IRR=infusion-related reaction; SAE=severe adverse event; TEAE=treatment-emergent adverse event; WBC=white blood cell.

1. Cheng Y. ASTRUM-005: updated results of first-line serplulimab versus placebo combined with chemotherapy in extensive-stage small-cell lung cancer. Presented at: ESMO Asia; December 2, 2022; Singapore.
2. Data on File, Fosun Pharma USA.

ASTRIDE

Randomized, Open-Label, Phase 3 Study

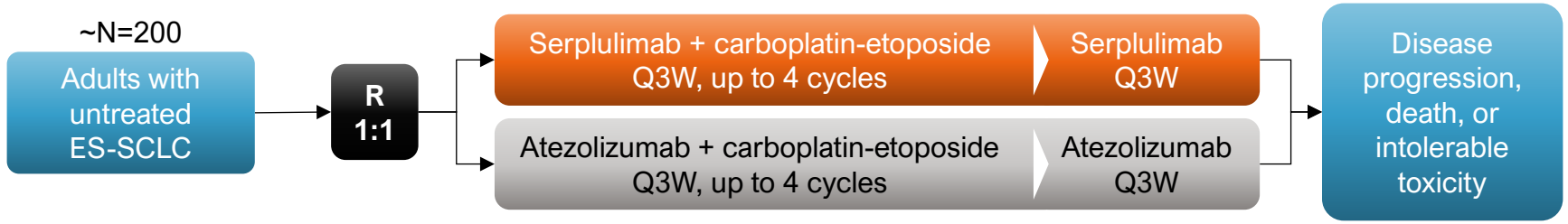
FOSUN PHARMA USA INC.

ASTRIDE: First Head-to-head, Open-Label, Phase 3 Study of Serplulimab vs Atezolizumab Added to Chemotherapy in Previously Untreated Patients With ES-SCLC in the US

FOSUN PHARMA USA INC.

This clinical trial is under investigation.

Study design: Phase 3, open-label, randomized, study



Key endpoints

Primary: OS

Secondary: PFS, ORR, DOR, QoL, PK, predictive biomarker analyses

Safety: AEs

Select inclusion criteria

- 18 years and older
- Histologically or cytologically diagnosed with ES-SCLC
- ≥1 measurable lesion
- Patients with treated and stable brain metastases may be enrolled
- ECOG PS 0 or 1
- No significant organ dysfunction
- Expected survival ≥12 weeks

Select exclusion criteria

- Histologically or cytologically confirmed mixed-stage SCLC
- Prior systemic SCLC treatments
- Grade ≥2 peripheral neuropathy
- LVEF <50% or NYHA class III to IV cardiac insufficiency
- Pregnant or breastfeeding females

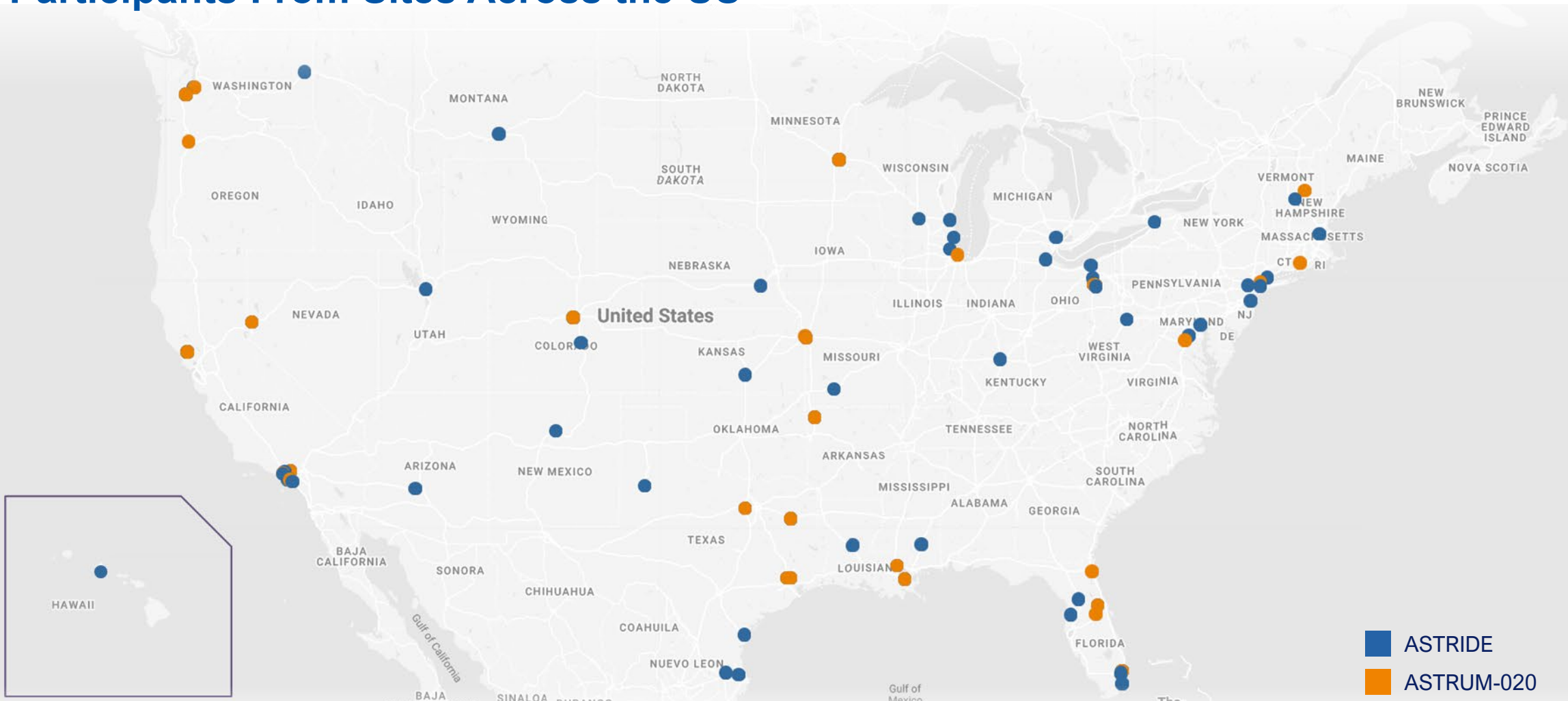
AE=adverse event; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group performance status; ES-SCLC=extensive-stage small cell lung cancer; LVEF=left ventricular ejection fraction; NYHA=New York Heart Association; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; PK=pharmacokinetics; Q3W=every 3 weeks; QoL=quality of life; R=randomized; SCLC=small cell lung cancer.

Data on File, Protocol HLX10-005-SCLC301-E, Fosun Pharma USA.

Phase 3 ASTRIDE Study

Currently Recruiting Participants, Enrolling an Estimated 200 Participants From Sites Across the US

FOSUN PHARMA USA INC.



Henlius USA Inc. Study Sites. Accessed April 2, 2024. https://www.smallcelllungcancertrial.com

ASTRUM-020

Randomized, Double-Blind, International, Multicenter, Phase 3 Study

ASTRUM-020 is active and currently enrolling patients in the US.

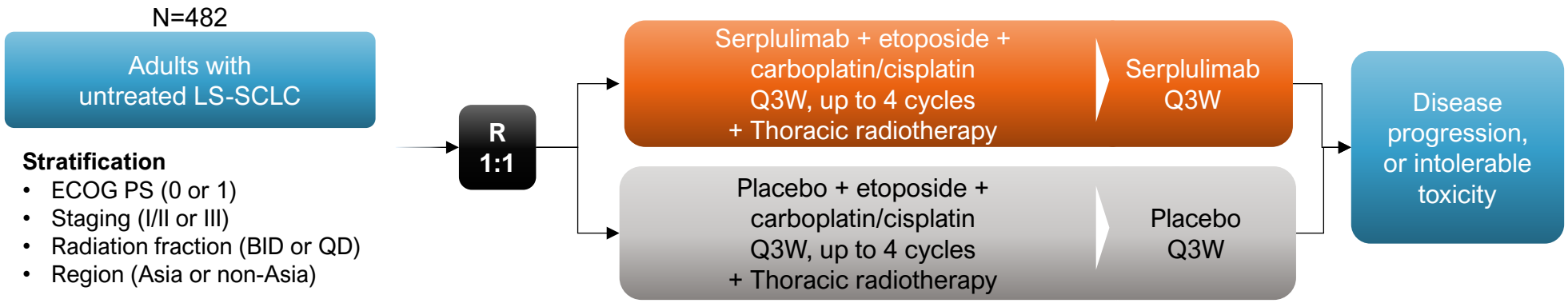
FOSUN PHARMA USA INC.

SER-MED-001-v2.0-08/2024

ASTRUM-020: Randomized, Double-Blind, International, Multicenter, Phase 3 Study of Serplulimab vs Placebo Added to Chemotherapy and Concurrent Radiotherapy in Previously Untreated Patients With LS-SCLC

FOSUN PHARMA USA INC.

Study design: Phase 3, double-blind, placebo-controlled, randomized study



Key endpoints

Primary: OS

Secondary: PFS

Key inclusion criteria

- Adult patients with LS-SCLC (stage I-III) who can be safely treated with curative radiation doses
- Adequate organ function

Key exclusion criteria

- Mixed-stage SCLC
- Surgical candidates
- Prior systemic SCLC treatments

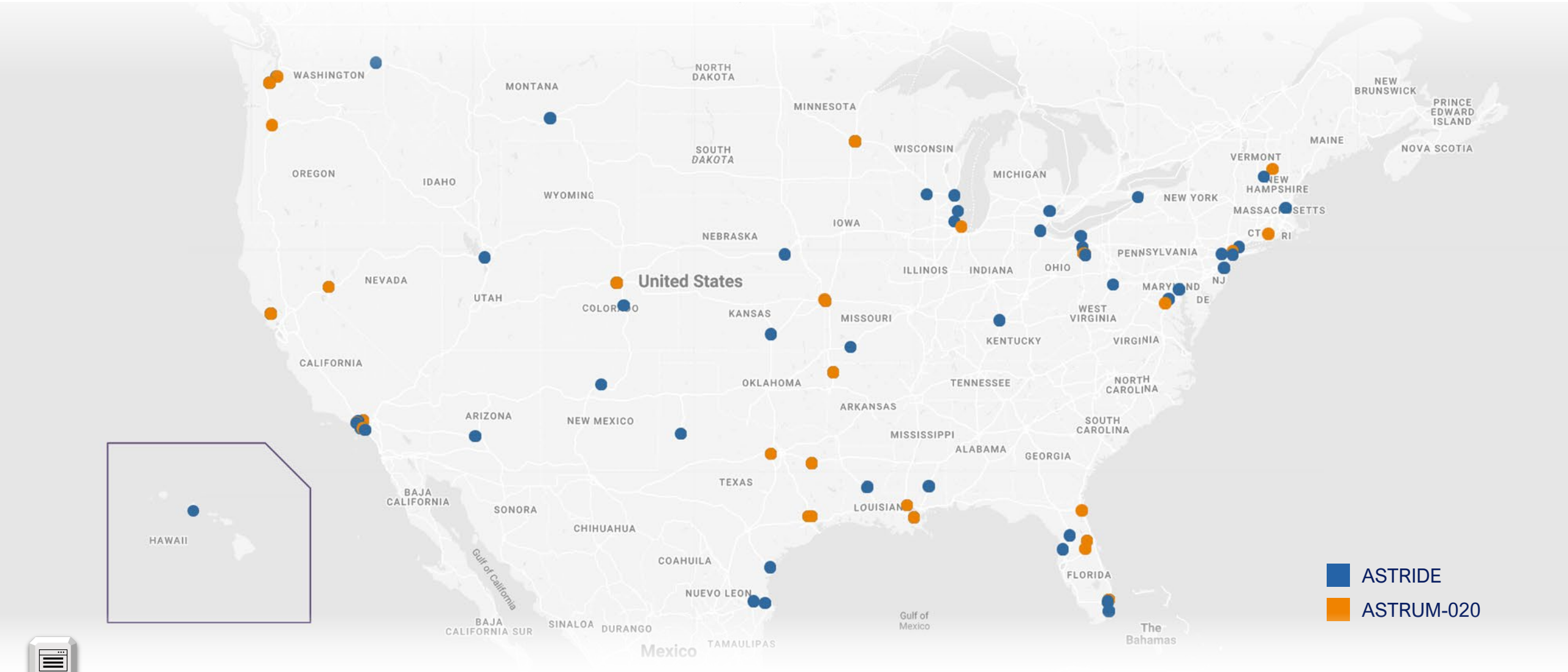
ASTRUM-020 is active and currently enrolling patients in the US

BID=twice daily; ECOG PS=Eastern Cooperative Oncology Group performance status; LS-SCLC=limited-stage small cell lung cancer; OS=overall survival; PFS=progression-free survival; Q3W=every 3 weeks; QD=once daily; R=randomized; SCLC=small cell lung cancer.

ClinicalTrials.gov. NCT05353257. Accessed October 16, 2023. https://clinicaltrials.gov/ct2/show/NCT05353257

Phase 3 ASTRUM-020 Study

Currently Recruiting Participants Across the US



Henlius USA Inc. Study Sites. Accessed April 2, 2024. https://www.smallcelllungcancertrial.com