RYBREVANT® ▼ (amivantamab)

LAZCLUZE® ▼ (lazertinib)

Tablets | 240 mg/80 mg

RYBREVANT® SC Q2W + LAZCLUZE® in *EGFR*m aNSCLC: Updates from PALOMA-2[1]

KEY TAKEAWAY

The **efficacy of RYBREVANT® SC Q2W + LAZCLUZE®** is consistent with the RYBREVANT® IV formulation, with the ***added tolerability and convenience of an SC formulation***, allowing patients to remain on treatment longer[1,2]

BACKGROUND

In patients with *cEGFRm* aNSCLC

RYBREVANT® SC Q2W + LAZCLUZE® vs RYBREVANT® IV formulation demonstrated:

- **~5-minute SC administration** per injection*[3]
- **~5x reduction in ARRs**[†3,4]
- **Noninferior pharmacokinetics** and response rates[3,4]

METHODS[1]

PALOMA-2 Cohort 1

Patients with previously untreated *cEGFRm* NSCLC

1L RYBREVANT® SC Q2W + LAZCLUZE®

Exon19del/L858R

- Prophylactic anticoagulation recommended (not mandated) for the first 4 months
- No specified prophylactic dermatologic management

Key eligibility criteria

- aNSCLC
- If brain metastases are present, they must be stable[‡]
- ECOG PS score of 0 or 1

ORR based on RECIST v1.1

ARR defined per the MedDRA Preferred Terms

Premedication for ARRs included 10 mg of dexamethasone or equivalent administered on C1D1

Primary endpoint:

- ORR by INV (*presented at ASCO 2024*)[5]

Secondary endpoints:

- ORR by ICR
- DoR by INV
- TTR by INV
- CBR by INV[§]
- PFS
- OS
- Safety
- PK

Dosing (in 28-day cycles)

RYBREVANT® SC Q2W:

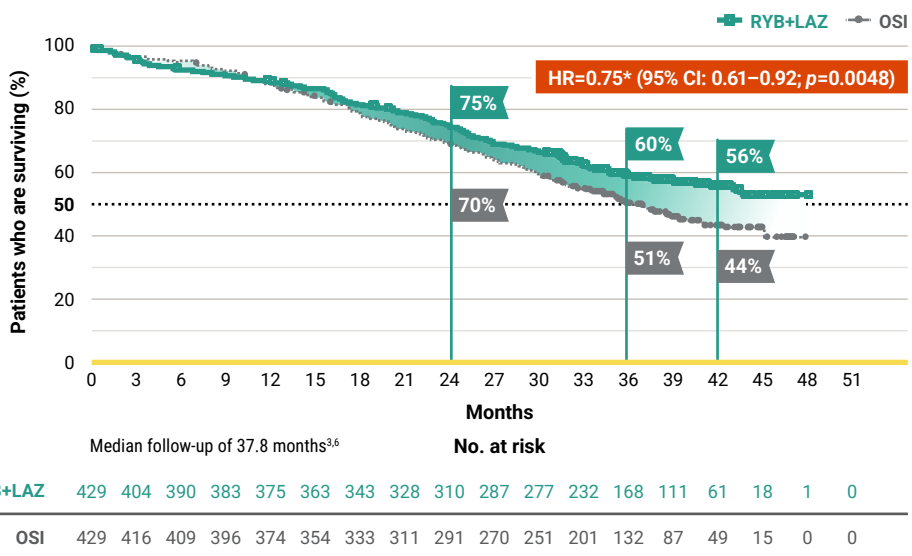
- SC abdominal injection at 1,600 mg (2,240 mg if ≥80 kg) weekly for 4 weeks, then Q2W

LAZCLUZE®: 240 mg orally daily

Cohort 1 (N=68) median follow-up: 32.2M, overall median treatment duration: 28.0M, with 30 patients (44%) remaining on treatment at data cutoff.
Please refer to the RYBREVANT® SPC for full premedication requirements.

PROVEN DURABLE SURVIVAL

Substantially extending patient life compared with osimertinib at clinical landmarks[6,7]



MARIPOSA is a Phase III study evaluating RYB+LAZ (n=429) compared with OSI monotherapy (n=429) in patients with cEGFRm advanced NSCLC.

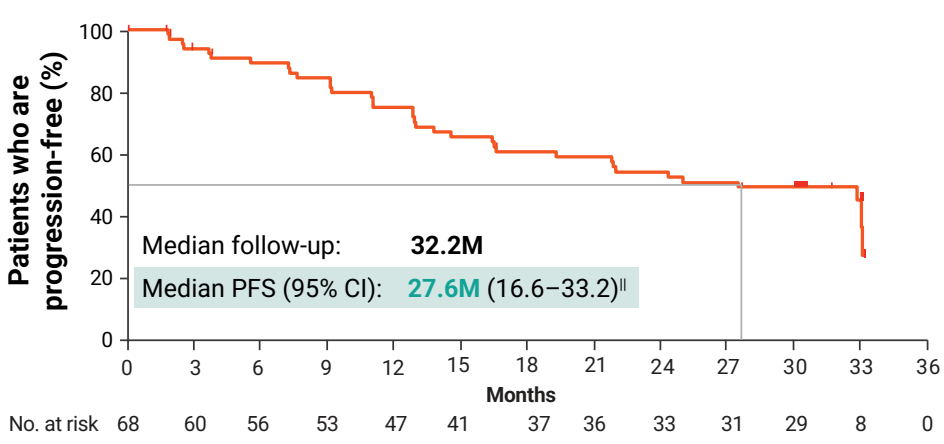
PROGRESSIVE WIDENING OF THE CURVES
when comparing RYB+LAZ vs. OSI[6]

mOS not reached and projected to exceed 4 YEARS
mOS was NE with RYB+LAZ vs. 36.7 months with OSI[6]

Primary endpoint achieved: mPFS was 23.7 months (95% CI: 19.1–27.7) with RYB+LAZ vs. 16.6 months (95% CI: 14.8–18.5) with OSI[2,3,8] HR=0.70 (95% CI: 0.58–0.85; *p*=0.0002)
*Hazard ratio reflects the OS benefit observed at 3 years for RYB+LAZ vs. OSI; HR was calculated from a stratified Cox regression model.[6,7]
CI, confidence interval; HR, hazard ratio; LAZ, LAZCLUZE®; mOS, median overall survival; mPFS, median progression-free survival; NE, not estimable; OS, overall survival; OSI, osimertinib; PFS, progression-free survival; RYB, RYBREVANT®.

RESULTS

Long-term durable outcomes demonstrated with 1L RYBREVANT® SC Q2W + LAZCLUZE® consistent with RYBREVANT® IV + LAZCLUZE®[1,2]



OS data were immature at the cutoff date:[1]

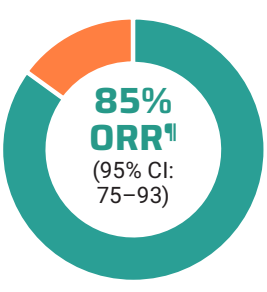
- 94% of patients were alive at 12M (95% CI: 85–98)
- 88% of patients were alive at 18M (95% CI: 77–94)

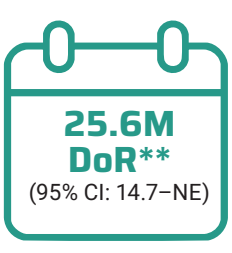
Among patients who received prophylactic anticoagulation, **2% had a Grade ≥3 VTE**[††1]

Most AEs occurred in the first 4M[1]

The safety profile was consistent with prior reports, with no new safety signals identified[1]

Responses were rapid and sustained





RYBREVANT® (amivantamab) is indicated, in combination with LAZCLUZE® (lazertinib), for the 1L treatment of adult patients with aNSCLC with ***EGFR*** Exon 19 deletions or Exon 21 L858R substitution mutations.[3]

▼ These medicinal products are subject to additional monitoring. This will allow quick identification of new safety information. HCPs are asked to report any suspected adverse reactions. See section 4.8 of the SmPCs for how to report adverse reactions.[3,8]

*~5-minute administration per SC injection is per syringe; vs 2–5 hours for IV infusion.[3]

[†]~5x reduction observed in PALOMA-3: ARRs were reported in 13% of patients treated with RYBREVANT® SC formulation in combination with LAZCLUZE® (N=206) compared to 66% with RYBREVANT® IV formulation in combination with LAZCLUZE® (N=212).[4]

[‡]Includes asymptomatic or previously treated participants with stable brain metastases.[1]

[§]CBR was defined as confirmed response or stable disease for ≥11 weeks.[1]

[‖]Median PFS was 27.6 months (95% CI: 16.6–33.2); RYBREVANT® IV + LAZCLUZE® in MARIPOSA median PFS was 23.7 months (95% CI: 19.1–27.7) at a median follow-up of 22.0 months by blinded ICR.[1]

[¶]ORR (confirmed and unconfirmed) was 85% (95% CI: 75–93) by ICR, consistent with RYBREVANT® IV + LAZCLUZE® in MARIPOSA: ORR of 86% (95% CI: 83–89) by blinded ICR.[1]

**Median DoR was 25.6 months (95% CI: 14.7–NE), and 47% had an ongoing response at the time of data cutoff (confirmed responders only; consistent with RYBREVANT® IV + LAZCLUZE® in MARIPOSA: 25.8 months [95% CI: 20.3-33.9]).[1]

[††]VTE events, including deep venous thrombosis (DVT) and pulmonary embolism (PE), were reported in 11% of patients receiving Rybrevant subcutaneous formulation in combination with lazertinib in PALOMA-2 and PALOMA-3. Most cases were Grade 1 or 2, with Grade 3 events occurring in 3 (0.9%) patients. Additionally, 269 (81%) of these 331 patients receiving Rybrevant subcutaneous formulation took prophylactic anticoagulants with a direct oral anticoagulant or low molecular weight heparin within the first four months of study treatment. In PALOMA-3, the incidence of VTE reactions was 9% for patients treated with Rybrevant subcutaneous formulation in combination with lazertinib, compared to 13% when treated with Rybrevant intravenous formulation in combination with lazertinib, with similar rates of prophylactic anticoagulant use in both treatment arms (80% in the subcutaneous arm vs. 81% in the intravenous arm). For patients who did not receive prophylactic anticoagulants, the overall incidence of VTE was 17% for patients treated with Rybrevant subcutaneous formulation in combination with lazertinib with all VTE reactions reported as Grade 1-2 and serious VTE reactions reported in 4.8% of these patients, compared to an overall incidence of 23% for patients treated with Rybrevant intravenous formulation in combination with lazertinib with Grade 3 VTE reactions reported in 10% and serious VTE reactions reported in 8% of these patients.[3]

1L, first-line; **AE,** adverse event; **aNSCLC,** advanced NSCLC; **ARR,** administration-related response; **ASCO,** American Society of Clinical Oncology; **C,** cycle; **CBR,** clinical benefit rate; **cEGFRm,** common EGFR-mutated; **CI,** confidence interval; **D,** day; **DoR,** duration of response; **ECOG PS,** Eastern Cooperative Oncology Group performance status; **EGFR,** epidermal growth factor receptor; **EGFRm,** EGFR-mutated; **Ex19del,** exon 19 deletion; **Ex20ins,** exon 20 insertion; **HCP,** healthcare professional; **ICR,** independent central review; **INV,** investigator; **IV,** intravenous; **L858R,** exon 21 L858R substitution; **M,** month; **MedDRA,** Medical Dictionary for Regulatory Activities; **NE,** not estimable; **NSCLC,** non-small cell lung cancer; **ORR,** objective response rate; **OS,** overall survival; **PFS,** progression-free survival; **PK,** pharmacokinetics; **Q2W,** every 2 weeks; **RECIST,** Response Evaluation Criteria in Solid Tumors; **SC,** subcutaneous; **TTR,** time to response; **VTE,** venous thromboembolic event.

Click **here** to learn more about the benefits of RYBREVANT® + LAZCLUZE®

References: 1. Girard N, et al. Presented at European Lung Cancer Congress, 25–28 March 2026; Copenhagen, Denmark. Poster 13P. **2.** Cho BC, et al. N Engl J Med. 2024;391(16):1486–1498. **3.** RYBREVANT® Saudi Summary of Product Characteristics. April 2025. **4.** Leighl NB, et al. J Clin Oncol. 2024;42(30):3593–3605. **5.** Lim SM, et al. Presented at: American Society of Clinical Oncology Annual Meeting; May 31–June 4, 2024; Chicago, IL, USA. **6.** Yang JC et al. N Engl J Med. 2025 (ePub ahead of print).doi: 10.1056/NEJMoa2503001. (Supplement. DOI: 10.1056/NEJMoa2503001). **7.** Yang JC et al. Presented at: European Lung Cancer Congress (ELCC) 2025. Abstract #40. **8.** LAZCLUZE® Saudi Summary of Product Characteristics. November 2024.

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