FP1506TIP

A SINGLE-ARM, PHASE 2 STUDY OF AMIVANTAMAB (AMI), LAZERTINIB (L) AND PEMETREXED (P) FOR FIRST-LINE TREATMENT OF RECURRENT/METASTATIC NON-SMALL CELL LUNG CANCERS (NSCLCS) WITH EGFR MUTATIONS IN EXONS 19 0R 21 (EGFR 19/21): AMIGO-1 (LACOG0821)

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BACKGROUND

- Osimertinib (OSI) is the current first-line standard treatment for patients with NSCLCs with EGFR 19/21.
- Data suggest that combining EGFR tyrosine kinase inhibitor (TKI) with chemotherapy may be superior to a sequential approach of first-line TKI followed by salvage therapy.
- AMI is an EGFR/MET bi-specific antibody currently approved for NSCLCs with EGFR exon 20 insertions. AMI is also being evaluated for NSCLCs with EGFR 19/21 in combination with chemotherapy (MARIPOSA-2 study) +/- L after OSI progression.

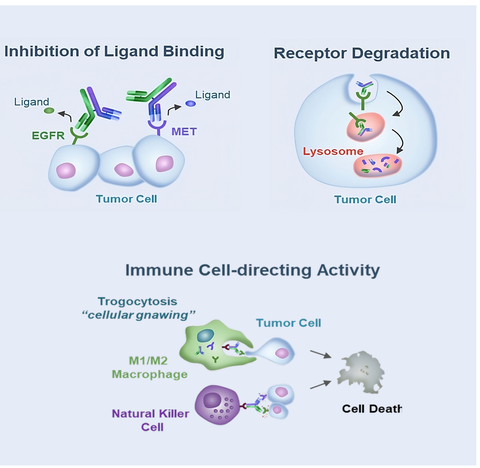

Figure 1. Mechanism of action of AMI and L. Cho, et al. ASCO 2021 (adapted).

STUDY HYPOTHESIS

In the first-line setting, the triplet regimen of AMI, combined with the 3rd generation irreversible TKI L, and P will improve progression-free survival (PFS) compared to historical controls, with an acceptable safety profile.

METHODS

- **LACOG 0821 AMIGO 1 (NCT05299125) is a single-arm, phase 2, multicenter trial.**
- Recruitment began in May 2023 in 11 research sites in Brazil (Figure 2). By September 2023, 20 patients have been included.

Primary Endpoint: **18-month PFS**

Secondary Endpoints: ORR, OS, 24-month PFS, PFS after first subsequent therapy, Performance Status at PFS1 and PFS2, Post-progression Therapies, Intracranial PFS, Patient-reported Outcomes, Safety and Toxicity

Exploratory Endpoints: Predictive biomarkers of response/survival

ELIGIBILITY CRITERIA

- Age ≥ 18 Years
- NSCLC, histologically confirmed
- Recurrent/metastatic disease
- Treatment-naïve
- EGFR mutations (exon 19 deletion or exon 21 L858R)

(N=49)

CYCLE 1 (21-days)

Amivantamab
1400 mg (1750 mg if ≥ 80 kg) IV
on day 1, 8 and 15
+
Lazertinib
240 mg PO daily
+
Pemetrexed
500 mg/m^2 IV on day 1

CYCLE 2 (21-days)

Amivantamab
1400 mg (1750 mg if ≥ 80 kg) IV
on day 1
+
Lazertinib
240 mg PO daily
+
Pemetrexed
500 mg/m^2 IV on day 1

CYCLES 3 + (21-days)

Amivantamab
1750 mg (2100 mg if ≥ 80 kg) IV
on day 1
+
Lazertinib
240 mg PO daily
+
Pemetrexed
500 mg/m^2 IV on day 1
Until PD or unacceptable toxicity

LACOG 0821 AMIGO-1
Sites

Figure 2. Study recruitment sites.

Statistical Considerations

- A one-group chi-square test with a type I error of 0.1 (one-sided) will have 80% power to detect the difference between the null hypothesis (18m-PFS of 50%, achieved with OSI alone) and the alternative hypothesis (18m-PFS of 65%) with a sample size of 49.

Conclusions

- AMIGO-1 is the first study to assess the triplet regimen of lazertinib, amivantamab, and pemetrexed as first-line treatment for NSCLCs with EGFR mutations.
- AMIGO-1 will provide benchmark results to be contrasted with the present standard of care and treatment combinations under development in phase 3 trials (eg. FLAURA2, MARIPOSA).

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