IFCT-0504 trial: Mucinous (M) and non-mucinous (NM) cytological subtypes interaction effect in first-line treatment of advanced bronchioloalveolar carcinoma (BAC), by erlotinib (E) or carboplatin/paclitaxel (C/P)


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ABSTRACT

Background: In IFCT-0401 trial, BAC patients, treated by erlotinib (E) or carboplatin/paclitaxel (C/P), had a significantly improved progression-free survival (PFS) compared to historical control (C/P). This trial involved patients with adenocarcinoma with predominant bronchioloalveolar carcinoma (BAC) and performed pathologically new review to better classify this tumor type. To our knowledge, no study has been conducted to analyze the interaction of mucinous vs non-mucinous adenocarcinoma in patients with advanced BAC treated with E or C/P.

Methods:

Inclusion criteria: Previously untreated, cyto/pathologically proven 75 22% 60% 4 mo. 17 mo. 75 22% 60% 4 mo. 17 mo. 6-month : 40.6% [32.1%- 48.9%] 1-year : 24.2% [17.2%-31.8%] .

Results:

133 patients enrolled. All patients reviewed by clinical trial panel. By centrally reviewed pathological reassessment, 132 (99.2%) were confirmed as adenocarcinoma with predominant BAC. Fifty-nine (44.4%) patients were classified as mucinous BAC.

Characteristics of the 133 patients included:

- Median age: 68 (range 20-83) years
- Performance status: 75 (56.4%) 0 = 116 (87%); 1 = 17 (13%)
- Female: 49 (37.0%)
- Never smokers: 57 (42.9%)
- Adenocarcinoma with predominant BAC (WHO classification 2004): 132 (100%) 2-step Fleming design (1-step of 30 pts and a second of 30 additional pts in each arm)

Factors associated with DCR at 4 months

Drug exposures

Feasibility – Significant Toxicities

CONCLUSIONS

IFCT-0504 trial showed that:

- Overall survival (OS) from 13.4 months in IFCT-0401 trial to 20.1 months in IFCT-0504 trial

+12.7 months improvement in OS, 2.3 months in PFS in mucinous BAC patients, with a 52% disease control rate at 4 months.

+2-step Fleming design (1-step of 30 pts and a second of 30 additional pts in each arm)

- Study 2: IFCT-0504, n=133

- Overall survival

- Progression-free survival

- Drug exposure

- Feasibility – Significant Toxicities