Class III β-tubulin (βT3) expression is a prognostic marker in patients with resectable non-small cell lung cancer (NSCLC) treated by perioperative chemotherapy (CT) in the phase III trial IFCT-0002.


Intergroupe Francophone de Cancérologie Thoracique (IFCT) - Paris – France

β T3 Immunostaining score

All specimens were evaluated by three experienced pathologists (MA, FGS & EB)

A composite score was determined for each slide:

1. % of tumoral stained cells
2. Lack of any staining
3. Basal staining compared with internal control
4. Intermediate staining compared with internal control
5. Strong staining compared with internal control
6. Continuous variable, range: 0-200

INTENSITY EVALUATION

β-tubulin is a component of mitotic spindle

RESULTS

βT3 Immunostaining predicts non-responsiveness to chemotherapy in univariate but not in multivariate analyses

Primary endpoint: overall survival between 2 treatment strategies
Secondary endpoints: RR, toxicity, QOL
Study of Biological Markers pre-planned and exploratory biological subset analyses pre-specified

CONCLUSIONS

Bio-IFCT 0002 is the first IHC analysis performed in a phase 3 trial of neoadjuvant chemotherapy in early lung cancer

- Such IHC analyses are feasible in this setting since 94% of the included patients could have their IHC analyzed of tumor specimens, making this sub-group fully representative of the whole cohort
- Pre-planned analyses with adapted statistical correction for multiple analyses identified a poor prognostic subset of stage I-II patients with high expression of class III β-tubulin

βT3 staining score

- Tubulin 3 immunostaining correlates with:

- Clinical benefit
- Disease-Free Survival (DFS)
- Overall Survival (OS)

• Predictive value: molecular characteristic status / attributed treatment (ITT)

\* P-values corrected for multiple comparisons (p*) according to the Hochberg method

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- Prognostic value: clinical characteristic status / attributed treatment (ITT)

- Adjusted for non-response
- Median follow-up at time of analysis (Jer 2008): 59 months
- Comparison of patients with or without a clinical response is achieved by the Cox model
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