

Overall survival interim analysis of a Phase III study of atezolizumab vs best supportive care in resected NSCLC

August 8 2022



Dr. Enriqueta Felip, Vall d'Hebron University Hospital, Vall d'Hebron Institute of Oncology, Barcelona, Spai. Credit: Dr. Enriqueta Felip, Vall d'Hebron University Hospital, Vall d'Hebron Institute of Oncology, Barcelona, Spai

An interim analysis of overall survival data from the IMpower010 trial showed an overall survival trend in favor of atezolizumab in the PD-L1 TC > 1% stage II-IIIa population (OS HR, 0.71 [95% CI: 0.49, 1.03]), but not in the all randomized stage II-IIIa or intent-to-treat population, according to research presented today at the IASLC World Conference on Lung Cancer 2022 in Vienna.

The highest magnitude of OS improvement was observed in people with stage II-IIIa disease whose tumors expressed PD-L1 TC ≥ 50% (HR=0.43, 95% CI: 0.24-0.78).

IMpower010 previously showed a statistically significant disease-free survival benefit with adjuvant [atezolizumab](#) compared with best supportive care in [patients](#) with resected [non-small cell lung cancer](#) following platinum-based chemotherapy. Based on these findings, atezolizumab was approved as adjuvant treatment after complete resection and platinum-based chemotherapy in patients with programmed death-ligand 1 (PD-L1) tumor cell (TC) ≥ 1% stage II-IIIa NSCLC in the United States, China, and other countries; and in PD-L1 TC ≥ 50% stage II-IIIa NSCLC in the European Union (excluding EGFR/ALK+) and other countries

The key secondary overall survival endpoint was not mature at the IMpower010 DFS interim analysis. Today data evaluating overall survival and safety with 13 months of additional follow-up were presented. "With an event to patient ratio of 25% in the ITT [population](#), the OS data are not mature, but are of clinical interest in this curative setting", said Dr. Enriqueta Felip, Vall d'Hebron University Hospital, Vall d'Hebron Institute of Oncology, Barcelona, Spain.

Eligible patients had completely resected stage IB (tumors ≥ 4 cm)-IIIa NSCLC (AJCC/UICC v7) and ECOG PS 0-1. Patients received one to four, 21-day cycles of cisplatin-based doublet chemotherapy (enrolment

phase) and were subsequently randomized 1:1 to receive 16 cycles of atezolizumab 1200 mg once every three weeks or best supportive care (randomization phase). The primary endpoint was disease-free survival hierarchically tested in 3 prespecified populations (PD-L1 TC $\geq 1\%$ stage II-III A population, all randomized stage II-III A population and ITT population (stage IB-III A)); secondary endpoints included overall survival among the intent to treat population and safety outcomes. This analysis constitutes the first pre-specified OS IA; OS in the ITT population will only be formally tested if DFS in that population reaches [statistical significance](#) at the final DFS analysis.

At the clinical cutoff date (18 April 2022), median follow-up was 45 months and 25% of patients had died (ITT population; N=1005). An overall survival trend in favor of atezolizumab was observed in the PD-L1 TC $\geq 1\%$ stage II-III A population. Adverse events of Grade 3-4 occurred in 22% of the atezolizumab arm and 11.5% of the best supportive care arm and led to atezolizumab discontinuation in 18.2% of patients. Grade 5 treatment-related adverse events occurred in 0.8% of patients who received atezolizumab and 0% in the best supportive care arm. Adverse events of special interest occurred in 52.1% of atezolizumab-treated patients, 7.9% were Grades 3-4.

"This OS analysis shows a promising trend in favour of atezolizumab over BSC in the PD-L1 TC $\geq 1\%$, stage II–III A population and a clinically meaningful improvement in the PD-L1 TC $\geq 50\%$, stage II–III A population, with the OS improvements observed across most subgroups. No separation was observed for the ITT population or the all-randomized, stage II–III A populations, and we will continue to follow patients in this study as data mature", said Dr. Felip, adding that IMpower010 will continue to the final disease-free survival analysis and further overall survival analyses.

Provided by International Association for the Study of Lung Cancer

Citation: Overall survival interim analysis of a Phase III study of atezolizumab vs best supportive care in resected NSCLC (2022, August 8) retrieved 1 February 2024 from <https://medicalxpress.com/news/2022-08-survival-interim-analysis-phase-iii.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.