Additionally, hazard ratio might be more indicative of the PFS benefit than single timepoint medians. The improvement in hazard ratio for PFS with sotorasib in the CodeBreaK 200 trial (NCT04303780) was not inferior to that of docetaxel plus ramucirumab in the REVEL trial.[1,2]

Clinical guidelines recommend taxanes, such as docetaxel, for patients whose non-small-cell lung cancer (NSCLC) progresses after checkpoint inhibitor or platinum-based chemotherapy.[3] Docetaxel as a monotherapy remains a widely accepted salvage for advanced NSCLC after first-line therapy.[4] Docetaxel with ramucirumab is not widely used in Europe.[5] Following discussion with several regulatory agencies, the CodeBreaK 200 trial included docetaxel as a globally accepted comparator.

Amgen (Thousand Oaks, CA, USA) originally designed CodeBreaK 200 to be powered for PFS and overall survival. The CodeBreaK 200 trial was amended based on emerging data from the CodeBreaK 100 trial and feedback from global regulatory agencies and investigators to maximise the number of patients receiving sotorasib. The key changes introduced a crossover from docetaxel to sotorasib and reduced sample size from 650 to 330 patients by powering for PFS only. PFS is an accepted surrogate in advanced NSCLC.

Baseline characteristics of patients randomly assigned to the docetaxel group who dropped out from the study and did not receive a dose of docetaxel showed poorer prognosis compared with patients treated with docetaxel in the trial (appendix). It is speculative to comment on the resources available to patients who dropped out of the study.

Ten (6·3%) of 158 patients receiving sotorasib and 12 (9·3%) of 129 patients receiving docetaxel had an at least 20% increase from baseline in the sum of tumour diameters for best overall response.

The appropriate way to assess survival in a trial is not only to look at the number of deaths in each group, but also to assess the time to death, which accounts for censoring and is measured by the Kaplan-Meier estimate of overall survival. This time-to-event analysis yielded a hazard ratio of 1·01 (95% CI 0·77–1·33) and does not suggest any detriment to survival with sotorasib.

The higher incidence of fatal treatment-emergent adverse events was driven by disease progression during the treatment emergent adverse event reporting period. All-cause death was balanced between 63·3% for patients treated with sotorasib and 58·9% for patients treated with docetaxel. Non-disease progression fatal adverse events did not show any pattern to suggest increased risk of death due to toxicity with sotorasib.

All patient-reported outcome measures in CodeBreaK 200 were assessed on the first cycle day, before docetaxel or sotorasib administration. For a single instrument (EQ-5D-5L) not reported in *The Lancet*, the outcome was additionally measured on day 5 for selected cycles and showed similar findings to day 1.

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