

Clinical Data Summary

Blood-First Assay Screening Trial (BFAST)

*BFAST is the first prospective study to use only blood-based next generation sequencing (NGS) to detect specific fusions with the aim of selecting treatment for people with advanced non-small cell lung cancer (NSCLC), without the need for tissue biopsy.**

Results from Cohort A

Patients tested for *ALK* fusions and, if positive, treated with Alecensa[®] (alectinib)

2,219 patients received liquid biopsy testing at Foundation Medicine



119 patients tested positive for *ALK* fusions

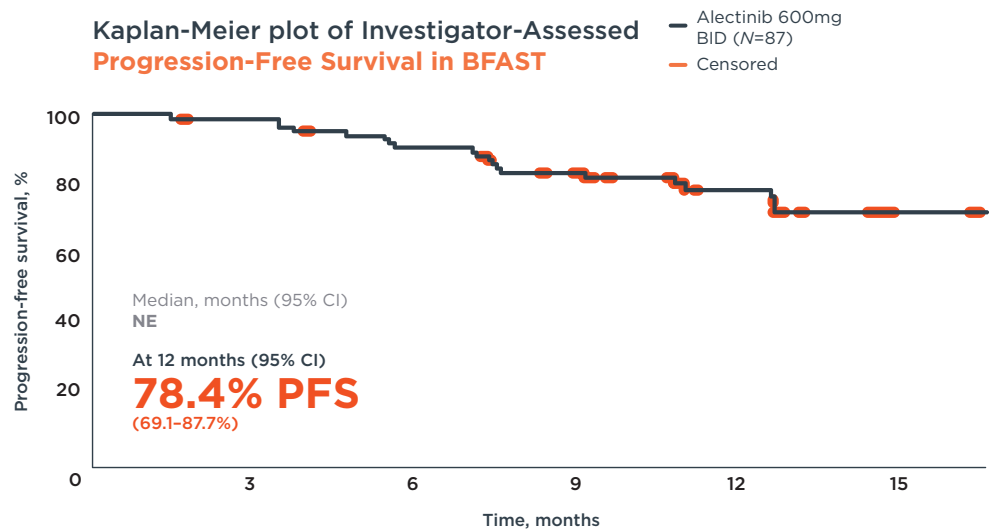


87 patients enrolled and treated with Alecensa[®] (alectinib)[†]



Study met its primary endpoint!

Kaplan-Meier plot of Investigator-Assessed Progression-Free Survival in BFAST



Frequency of ALK fusions in BFAST

FoundationOne Liquid is the only liquid biopsy test that has demonstrated the ability to identify patients with ALK fusions in a global prospective trial for metastatic NSCLC at similar frequencies historically published with tissue testing.

5.4%

frequency of ALK fusions in BFAST with FoundationOne Liquid

— vs. —

5%[‡]

frequency of ALK fusions using tissue testing historically published



36 institutions,
15 countries

FoundationOne Liquid is the first and only liquid biopsy test to show prospective clinical utility in a global registrational trial for patients with newly diagnosed, metastatic NSCLC.

FoundationOne Liquid is a laboratory developed test that was developed and its performance characteristics determined by Foundation Medicine.

Foundation Medicine is the only company with a proven portfolio of comprehensive genomic profiling tests—from a blood draw or tissue biopsy—that has demonstrated clinical utility in metastatic, newly diagnosed NSCLC.[¶]



Fast results in less than two weeks[†]



Tests include guideline-recommended genes in NSCLC

EGFR | ALK | ROS1 | BRAF | RET | MET | ERBB2



Simplified and expertly curated reports to help inform clinical decision making

References

* LBA81_PR 'Phase II/III blood first assay screening trial (BFAST) in patients (pts) with treatment-naïve NSCLC: initial results from ALK+ cohort' will be presented by Shirish Gadgeel during the proffered paper session on Monday, 30 September 2019, 08:30-10:00 CEST in Madrid Auditorium (Hall 2). Annals of Oncology, Volume 30, Supplement 5, October 2019.

† There were 32 patients identified as ALK-Positive and not enrolled on the trial due to other ineligibility criteria, patient or investigator decision, or other reasons.

‡ Dearden et al. Ann Oncol. 2013 Sep; 24(9): 2371-2376.

¶ Typical turnaround time from receipt of specimen

* FoundationOne®Heme is excluded from this claim. FoundationOne Heme is a laboratory developed test that was developed and its performance characteristics determined by Foundation Medicine.