## INTRODUCTION

Alectinib is a poisons, highly selective, CSK-A positive AKR inhibitor that has been investigated in three Phase III trials in ALK-positive patients with ALK+ NSCLC. The ALEX trial (NCT02075840) was conducted in patients with ALK+ NSCLC who had not received prior treatment for metastatic disease.

## METHODS

### Patients

- **Alectinib arm**:
  - Total: 152 patients
  - Median age: 58 years
  - ECOG PS: 0–1 (93%)
  - Stage: IIIB/IV (62%)

- **Crizotinib arm**:
  - Total: 151 patients
  - Median age: 54 years
  - ECOG PS: 0–1 (93%)
  - Stage: IIIB/IV (62%)

### Treatment

- **Alectinib**: 600 mg twice daily
- **Crizotinib**: 250 mg twice daily

### Outcomes

- **Primary endpoint**: Investigator-assessed progression-free survival (PFS)
- **Secondary endpoints**: Overall survival (OS), safety, and efficacy

### Regimens

- **Alectinib and Crizotinib**:
  - **Alectinib**: 600 mg twice daily
  - **Crizotinib**: 250 mg twice daily

### Safety

- The safety profile of alectinib compared favorably with that of crizotinib, despite the longer duration of treatment.

### Efficacy

- Alectinib demonstrated superior efficacy versus crizotinib regardless of baseline CNS metastases.

## RESULTS

### Primary endpoint

- **Alectinib**: Median PFS was 34.8 months (95% CI: 29.7–NE)
- **Crizotinib**: Median PFS was 11.1 months (95% CI: 9.1–12.9) with crizotinib.

### OS

- The Kaplan-Meier method was used to estimate medians for each treatment arm with 95% confidence limits and every 8 weeks until PD.

### Tumor Reduction

<table>
<thead>
<tr>
<th>Table 2. Tumor reduction in responders (ITT and CNS subgroups).</th>
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<tbody>
<tr>
<td><strong>Alectinib (n=152)</strong></td>
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<tr>
<td><strong>Baseline</strong></td>
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<tr>
<td><strong>Tumor reduction</strong></td>
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<tr>
<td><strong>&gt;75% tumor reduction</strong></td>
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<td><strong>&gt;50% tumor reduction</strong></td>
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<td><strong>&gt;30% tumor reduction</strong></td>
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<td><strong>&gt;10% tumor reduction</strong></td>
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### Conclusion

- The updated analysis of ALEX data confirms that alectinib shows superior investigator-assessed PFS versus crizotinib, with a median PFS of 34.8 months.

## ACKNOWLEDGMENTS

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## REFERENCES

1. D. Ross Camidge, MD, PhD, MHCDS, FACP, FRCP, FRCPA, Clinical Director, Pink Ladies and Associates, Breast Cancer Foundation; and Faculty Member, Department of Medicine, University of Chicago. Supported by the Pink Ladies and Associates, Breast Cancer Foundation.