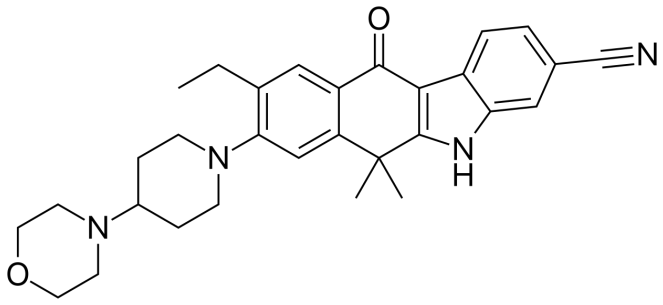
**Brand Name:** Alecensa
**Generic:** alectinib
**Type:** small molecule
**Year Accepted/Phase:** 2015

## Mechanism:

Alectinib is an ALK inhibitor that blocks the activity of the ALK protein, which is involved in the growth and spread of cancer cells. By inhibiting this protein, alectinib helps to stop or slow down the growth of ALK-positive cancer cells.

## Chemical Structure:




## Indication:

Alecensa is indicated for the treatment of patients with ALK-positive metastatic NSCLC.

## Clinical trials:

**Phase I/II Studies**
**Pubmed:** https://pubmed.ncbi.nlm.nih.gov/25153538/
**Purpose:** Evaluate the safety, pharmacokinetics, and preliminary efficacy of alectinib in patients with ALK-positive NSCLC.
**Dates:** Initial studies conducted in Japan with results published in 2013.
**Results:** These early studies demonstrated that alectinib was well tolerated and showed promising anti-tumor activity.

**AF-001JP (Japanese Phase II Trial)**
**Pubmed:** https://pubmed.ncbi.nlm.nih.gov/28296581/
**Purpose:** Assess the efficacy and safety of alectinib in Japanese patients with ALK-positive NSCLC who were resistant or intolerant to crizotinib.
**Dates:** Results published in 2014.
**Results:** The trial showed a high overall response rate (ORR) of 93.5%, leading to the approval of alectinib in Japan in 2014.

**NP28673 (Global Phase II Trial)**
**Pubmed:** https://pubmed.ncbi.nlm.nih.gov/28689043/
**Purpose:** Evaluate the efficacy and safety of alectinib in patients with ALK-positive NSCLC who had progressed on crizotinib.
**Dates:** Results published in 2015.
**Results:** The study demonstrated an ORR of 50%, with a median progression-free survival (PFS) of 8.9 months.

**NP28761 (North American Phase II Trial)**
**Pubmed:** https://pubmed.ncbi.nlm.nih.gov/28689043/
**Purpose:** Similar to NP28673, this trial assessed the efficacy of alectinib in patients with ALK-positive NSCLC who had progressed on crizotinib.
**Dates:** Results published in 2016.
**Results:** The ORR was 47.8%, with a median PFS of 8.1 months.

**ALEX Trial (Phase III)**
**Pubmed:** https://pubmed.ncbi.nlm.nih.gov/28586279/
**Purpose:** Compare the efficacy and safety of alectinib with crizotinib as a first-line treatment for patients with ALK-positive NSCLC.
**Dates:** Conducted from 2014 to 2017, with results published in 2017.
**Results:** Alectinib significantly improved PFS compared to crizotinib, with a median PFS of 34.8 months versus 10.9 months. It also showed a better side effect profile and reduced the risk of central nervous system (CNS) progression.

**J-ALEX Trial (Japanese Phase III)**
**Pubmed:** https://pubmed.ncbi.nlm.nih.gov/31812890/
**Purpose:** Compare alectinib with crizotinib in Japanese patients with ALK-positive NSCLC.
**Dates:** Results published in 2017.
**Results:** Similar to the global ALEX trial, alectinib showed a superior PFS (not reached versus 10.2 months for crizotinib).