

A Study Evaluating the Safety, Pharmacokinetics, and Efficacy of Alectinib in Pediatric Participants With ALK Fusion-Positive Solid or CNS Tumors

NCT04774718

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Hoffmann-La Roche
Enrollment	42 participants

Key Eligibility Criteria

Inclusion (9)

- Histologically confirmed diagnosis of CNS or solid tumors with documented evidence of ALK gene fusions as assessed centrally through the use of the investigational F1CDx assay or based on pre-existing NGS test results
 - Disease status: prior treatment proven to be ineffective (i.e. relapsed or refractory), or for whom there is no satisfactory standard treatment available. Disease should be measurable and evaluable as defined by Response Evaluation Criteria in Solid Tumors (RECIST) v 1.1, or Response Assessment in Neuro-oncology criteria (RANO) +/- bone marrow criteria for primary CNS tumors or International Neuroblastoma Response Criteria (INRC)
 - Available tumor tissue for submission to the Sponsor from active disease, obtained subsequent to last anti-cancer therapy regimen administered and obtained prior to study enrollment (preferred option), or archival tumor tissue from original diagnosis, or willingness to undergo a core or excisional biopsy sample collection prior to enrollment
 - For participants < 16 years old, Lansky Performance Status \geq 50%
 - For participants \geq 16 years old, Karnofsky Performance Status \geq 50%
- ... and 4 more (see full listing online)

Exclusion (13)

- Medical history of: prior use of ALK inhibitors; diagnosis of Anaplastic Large Cell Lymphoma (ALCL); any gastrointestinal disorder that may affect absorption of oral medications, such as mal-absorption syndrome or status post-major bowel resection; history of organ transplant; stem cell infusions as defined by the protocol
 - Substance abuse within 12 months prior to screening
 - Familial or personal history of congenital bone disorders, bone metabolism alterations, or osteopenia
 - Treatment with investigational therapy 28 days prior to initiation of study drug
 - Liver or kidney disease as defined by the protocol
- ... and 8 more (see full listing online)

Locations (33 total)

Lucile Packard Children's Hospital, Palo Alto, California, United States
Johns Hopkins All Children's Hospital, St. Petersburg, Florida, United States
University of Michigan, C.S. Mott Children's Hospital, Ann Arbor, Michigan, United States
... and 30 more locations

<https://clinicaltrials.gov/study/NCT04774718>

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