

Cyclin-Dependent Kinase (CDK)4/6 Inhibitor Abemaciclib for Neurofibromatosis Type I (NF1) Related Atypical Neurofibromas

NCT04750928

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	National Cancer Institute (NCI)
Enrollment	55 participants

Key Eligibility Criteria

Inclusion (44)

- All Participants
- Participants must have a clinical diagnosis of NF1, i.e., participants must have at least two of the diagnostic criteria for NF1 or a confirmed NF1 mutation from a CLIA-certified laboratory:
- Six or more café-au-lait macules (≥ 0.5 cm in prepubertal participants or ≥ 1.5 cm in post pubertal participants)
- Freckling in axilla or groin
- A neurofibroma or plexiform neurofibroma
- ... and 39 more (see full listing online)

Exclusion (14)

- Pregnant women, or women who intend to become pregnant during the study, are excluded from this study because of the teratogenic effects of abemaciclib. Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with these agents, breastfeeding should be discontinued if the mother is treated on study.
- May not have a NF1-related tumor such as optic pathway glioma or malignant peripheral nerve sheath tumor, which requires treatment with chemotherapy or surgery.
- Serious preexisting medical condition(s) that would preclude participation in this study (for example, interstitial lung disease, severe dyspnea at rest requiring oxygen therapy, history of major surgical resection involving the stomach or small bowel that would preclude adequate absorption, or preexisting Crohn's disease or ulcerative colitis or a preexisting chronic condition resulting in baseline Grade 2 or higher diarrhea).
- Uncontrolled intercurrent illness including, but not limited to, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, active bleeding diatheses or renal transplant, or psychiatric illness/social situations that would limit compliance with study requirements.
- Personal history of any of the following conditions: syncope of cardiovascular etiology, ventricular arrhythmia of pathological origin (including, but not limited to, ventricular tachycardia and ventricular fibrillation), or sudden cardiac arrest.
- ... and 9 more (see full listing online)

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States

<https://clinicaltrials.gov/study/NCT04750928>

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