ANHL2121: Phase 2 Study of Tovorafenib (DAY101) in Relapsed and Refractory Langerhans Cell Histiocytosis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 180 days to < 22 years (at time of study enrollment) - patients with multifocal progressive, relapsed, or recurrent LCH with measurable disease at study entry - participant must be able to take an enteral dose and formulation of medication. Study medication is only available as an oral suspension or tablet, which may be taken by mouth or other enteral route such as nasogastric, jejunostomy, or gastric tube - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- LCH arising along with other hematologic malignancy (e.g. mixed LCH with acute lymphoblastic leukemia) or any history of non-histiocytic malignancy - history of solid organ or hematopoietic bone marrow transplantation - female patients who are pregnant are ineligible. A pregnancy test is required for female patients of childbearing potential - lactating females who plan to breastfeed their infants are ineligible - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Conditions:
Cancer
Keywords:
LCH, Recurrent Langerhans Cell Histiocytosis, Refractory Langerhans Cell Histiocytosis

More Information

Description: This phase II trial tests the safety, side effects, best dose and activity of tovorafenib (DAY101) in treating patients with Langerhans cell histiocytosis that is growing, spreading, or getting worse (progressive), has come back (relapsed) after previous treatment, or does not respond to therapy (refractory). Langerhans cell histiocytosis is a type of disease that occurs when the body makes too many immature Langerhans cells (a type of white blood cell). When these cells build up, they can form tumors in certain tissues and organs including bones, skin, lungs and pituitary gland and can damage them. This tumor is more common in children and young adults. DAY101 may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. Using DAY101 may be effective in treating patients with relapsed or refractory Langerhans cell histiocytosis.
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Phase: PHASE2
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