

PEPN2312; A Phase 1 study of GRN163L (Imetelstat, IND# 170891, NSC# 754228) in combination with fludarabine and cytarabine for patients with acute myeloid leukemia that is in second or greater relapse or that is refractory to relapse therapy; myelodysplastic syndrome or juvenile myelomonocytic leukemia in first or greater relapse or is refractory to relapse therapy

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Up to 18 years old

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Between 1 year and less than 18 years of age at enrollment - Patients, with or without Down syndrome (DS), and with de novo acute myeloid leukemia, therapy-related AML, MDS or JMML. - In second or greater relapse or refractory AML or First or greater relapse of MDS, or First or greater relapse of JMML - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- Pregnant or breast-feeding - Currently receiving investigational drugs or other anti-cancer agents

Conditions & Interventions

Conditions:

Cancer

Keywords:

acute myeloid leukemia, AML, JMML, juvenile myelomonocytic leukemia, MDS, myelodysplastic syndrome

More Information

Description: This phase I trial tests the safety, side effects, and best dose of imetelstat in combination with fludarabine and cytarabine in treating patients with acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) or juvenile myelomonocytic leukemia (JMML) that has not responded to previous treatment (refractory) or that has come back after a period of improvement (recurrent). Imetelstat may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. Chemotherapy drugs, such as fludarabine and cytarabine, work in different ways to stop the growth of cancer cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Giving imetelstat in combination with fludarabine and cytarabine may work better in treating patients with refractory or recurrent AML, MDS, and JMML.

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Phase: PHASE1

IRB

Number: STUDY00022789

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