

A Study of Belumosudil in Children With Chronic Graft Versus Host Disease (schoolROCK)

NCT07116031

Status	RECRUITING
Phase	Phase 2
Sponsor	Sanofi
Enrollment	37 participants

Key Eligibility Criteria

Inclusion (11)

- Participant must be 1 to <18 years of age, at the time the consent/assent is signed. For Phase 1: participant must be 1 to <12 years of age, at the time the consent/assent is signed. For Phase 2: participant must be 1 to <18 years of age, at the time the consent/assent is signed.
 - Participant has undergone an allogeneic HCT
 - Has active moderate to severe cGVHD, defined using the NIH Consensus diagnosis and staging criteria for which systemic therapy is required
 - cGVHD is refractory to or has recurred after at least 2 prior lines of systemic treatment
 - Has received at least two lines of prior systemic therapy for cGVHD, but no more than 5 lines.
- ... and 6 more (see full listing online)

Exclusion (22)

- Progressive underlying disease or post-transplant lymphoproliferative disease within 4 weeks prior to the first dose of the IMP.
 - Diagnosed with another malignancy (other than malignancy for which transplant was performed) within 3 years prior to the first dose of the IMP
 - History or other evidence of severe illness or any other conditions that would make the participant, in the opinion of the Investigator, unsuitable for the study (such as malabsorption syndromes, active, uncontrolled infections, or poorly controlled psychiatric disease)
 - Has a forced expiratory volume (in the first second; FEV1) <39% or has lung score of 3
 - Female participants who are pregnant or breastfeeding
- ... and 17 more (see full listing online)

Locations (23 total)

Memorial Sloan Kettering Cancer Center - New York - York Avenue- Site Number : 8400001, New York, New York, United States
Texas Children's Hospital- Site Number : 8400008, Houston, Texas, United States
Investigational Site Number : 0560003, Ghent, Belgium
... and 20 more locations

<https://clinicaltrials.gov/study/NCT07116031>

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