Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

CR107947

Öffentlicher Titel	Phase 2/3-Studie zu Imetelstat bei Patienten mit niedriger/mittlerer-Risiko-MDS
Wissenschaftl. Titel	A Study to Evaluate Imetelstat (GRN163L) in Transfusion-Dependent Subjects With IPSS Low or Intermediate-1 Risk Myelodysplastic Syndrome (MDS) That is Relapsed/Refractory to Erythropoiesis-Stimulating Agent (ESA) Treatment
Kurztitel	CR107947
Studiennummer KN/ELN	LN_NN_2015_718
Studiengruppe	NN
Studienart	multizentrisch, randomisiert, mehrarmig, doppelblind
Studienphase	Phase II/III
Erkrankung	Myelodysplastisches Syndrom (MDS) - Niedrigrisko und Intermediär I
Leukämiestadium	.
Einschlusskriterien	- Man or woman greater than or equal to (>=) 18 years of age - In Part 1, diagnosis of myelodysplastic syndrome (MDS) according to World Health Organization (WHO) criteria - International Prognostic Scoring System (IPSS) low Risk or intermediate-1 risk MDS - Red blood cell (RBC) transfusion dependent, defined as requiring at least 4 RBC units transfused over an 8-week period during the 16 weeks prior to Study Entry; pre-transfusion hemoglobin (Hb) should be less than or equal to 9.0 gram per deciliter (g/dL) to count towards the 4 units total - Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2
Ausschlusskriterien	- Participant has known allergies, hypersensitivity, or intolerance to imetelstat or its excipients - Participant has received an investigational drug or used an invasive investigational medical device within 30 days prior to Study Entry or is currently enrolled in an investigational study - Prior treatment with Imetelstat - Have received corticosteroids greater than (>) 30 milligram per day (mg/day) prednisone or equivalent, or growth factor treatment within 4 weeks prior to study entry - a) Prior treatment with a hypomethylating agent (example [eg], azacitidine, decitabine); b) Prior treatment with lenalidomide; c) Has received an erythropoiesis-stimulating agent (ESA) or any chemotherapy, immunomodulatory, or immunosuppressive therapy within 4 weeks prior to study entry (8 weeks for long-acting ESAs)
Alter	>= 18 Jahre
Status	Aktiv
Beginn der Rekrutierung	06.11.2015
Sponsoren	Geron Corporation (Hauptsponsor)
Registrierung in anderen Studienregistern	ClinicalTrials.govNCT02598661 (primäres Register)