Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

INCB 54828-203

Öffentlicher Titel	Phase-II-Studie zu Pemigatinib bei Patienten mit myeloischen/lymphatischen Neoplasien mit FGFR-Umlagerung
Wissenschaftl. Titel	A Phase 2, Open-Label, Monotherapy, Multicenter Study to Evaluate the Efficacy and Safety of Pemigatinib (INCB054828) in Subjects With Myeloid/Lymphoid Neoplasms With FGFR1 Rearrangement - (FIGHT-203)
Kurztitel	INCB 54828-203
Studiennummer KN/ELN	LN_NN_2018_636
Studiengruppe	NN
Studienart	multizentrisch, prospektiv, offen
Studienphase	Phase II
Erkrankung	Myeloproliferative Neoplasien (MPN) - Alle Subtypen
Leukämiestadium	.
Einschlusskriterien	- Documented lymphoid or myeloid neoplasm with 8p11 rearrangement known to lead to FGFR1 activation, based on standard diagnostic cytogenetic evaluation performed locally, before signing informed consent for this study. - Subjects must be relapsed/refractory. Prior stem cell transplantation is allowed. - Life expectancy 12 weeks. - Eastern Cooperative Oncology Group (ECOG) performance status 0 to 2.
Ausschlusskriterien	- Prior receipt of a selective FGFR inhibitor. - History and/or current evidence of ectopic mineralization/calcification, including but not limited to soft tissue, kidneys, intestine, myocardia, or lung, except calcified lymph nodes and asymptomatic arterial or cartilage/tendon calcifications. - Current evidence of corneal disorder/keratopathy, including but not limited to bullous/band keratopathy, corneal abrasion, inflammation/ulceration, and keratoconjunctivitis, as confirmed by ophthalmologic examination. - Use of any potent cytochrome P450 3A4 inhibitors or inducers within 14 days or 5 half-lives (whichever is shorter) before the first dose of study drug.
Alter	>= 18 Jahre
Status	Aktiv
Beginn der Rekrutierung	10.10.2018
Sponsoren	Incyte Corporation
Registrierung in anderen Studienregistern	ClinicalTrials.govNCT03011372