KURZPROTOKOLL
REACH 3

Öffentlicher Titel	Phase III Studie zu Ruxolitinib bei steroidrefraktärer chronischer Graft-versus-Host-Erkrankung
Wissenschaftl. Titel	A phase III randomized open-label multi-center study of ruxolitinib vs. best available therapy in patients with corticosteroid-refractory chronic graft versus host disease after allogenic stem cell transplantation
Kurztitel	REACH 3
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Kinder: Leukämien und Lymphome: sonstige Studien für Leukämien und Lymphome im Kindesalter Blut: Stammzelltransplantation: Transplantat-gegen-Wirt-Reaktion (GvHD)
Einschlusskriterien	- Have undergone allogeneic stem cell transplantation (alloSCT) from any donor source (matched unrelated donor, sibling, haplo-identical) using bone marrow, peripheral blood stem cells, or cord blood. Recipients of non-myeloablative, myeloablative, and reduced intensity conditioning are eligible - Evident myeloid and platelet engraftment: Absolute neutrophil count (ANC) > 1000/mm^3 and platelet count > 25,000/ mm^3 - Participants with clinically diagnosed moderate to severe cGvHD according to NIH Consensus Criteria prior to randomization: - -> Moderate cGvHD: At least one organ (not lung) with a score of 2, 3 or more organs involved with a score of 1 in each organ, or lung score of 1 - -> Severe cGvHD: at least 1 organ with a score of 3, or lung score of 2 or 3 - Participants currently receiving systemic or topical corticosteroids for the treatment of cGvHD for a duration of < 12 months prior to Cycle 1 Day 1 (if applicable), and have a confirmed diagnosis of steroid-refractory cGvHD defined per 2014 NIH consensus criteria irrespective of the concomitant use of a calcineurin inhibitor (CNI), as follows: - -> A lack of response or disease progression after administration of minimum prednisone 1 mg/kg/day for at least 1 week, OR - -> Disease persistence without improvement despite continued treatment with prednisone at > 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks, OR - -> Increase to prednisolone dose to > 0.25 mg/kg/day after 2 unsuccessful attempts to taper the dose - Participant must accept to be treated with only one of the following BAT options on Cycle 1 Day 1 (additions and changes are allowed during the course of the study, but only with BAT from the following BAT options): extracorporeal photopheresis (ECP), low-dose methotrexate (MTX), mycophenolate mofetil (MMF), mTOR inhibitors (everolimus or sirolimus), infliximab, rituximab, pentostatin, imatinib, ibrutinib
Ausschlusskriterien	- Participants who have received 2 or more systemic treatment for cGvHD in addition to corticosteroids +- CNI for cGvHD - Patients that transition from active aGvHD to cGvHD without tapering off corticosteroids +- CNI and any systemic treatment - -> Patients receiving up to 30 mg by mouth once a day of hydrocortisone (i.e., physiologic replacement dose) of corticosteroids are allowed. - Participants who were treated with prior JAK inhibitors for aGvHD; except when the participant achieved complete or partial response and has been off JAK inhibitor treatment for at least 8 weeks prior to Cycle 1 Day 1 - Failed prior alloSCT within the past 6 months from Cycle 1 Day 1 - Participants with relapsed primary malignancy, or who have been treated for relapse after the alloSCT was performed

	- Steroid refractory cGvHD occurring after a non-scheduled donor lymphocyte infusion (DLI) administered for preemptive treatment of malignancy recurrence. Participants who have received a scheduled DLI as part of their transplant procedure and not for management of malignancy relapse are eligible - Any corticosteroid therapy for indications other than cGvHD at doses > 1 mg/kg/day methylprednisolone or equivalent within 7 days of Cycle 1 Day 1
Alter	12 Jahre und älter
Sponsor	Novartis Pharma
Registrierung in anderen Studienregistern	EudraCT 2016-004432-38 ClinicalTrials.gov NCT03112603 (primäres Register)
Links	Studiendokumente zum Download (roXtra)