Kompetenznetz "Akute und chronische Leukämien"

SHORTPROTOCOL

ENESTPath

Public Title	Study to Assess the Effect of a Longer Duration of Consolidation Treatment With Nilotinib on TFR in CP CML
Scientific Title	A Prospective, Randomized, Open Label, Two Arm Phase III Study to Evaluate Treatment Free Remission (TFR) Rate in Patients With Philadelphia-positive CML After Two Different Durations of Consolidation Treatment With Nilotinib 300mg BID
Short Title	ENESTPath
Id KN/ELN	LN_NN_2013_534
Trialgoup	NN
Type of Trial	multicentric, randomized, prospective, open-label, double-group
Phase	Phase III
Disease	Chronic myeloid leukemia(CML) Chronic Phase
Stage of Disease	.
Molecular Marker	BCR-ABL
Outcomes	- optimal duration of consolidation treatment with nilotinib 300 mg BID to ensure the highest rate of patients remaining in MR4.0 12months after entering the TFR phase. [Time Frame: 48 months] (Primary Outcome) - To evaluate the proportion of patients who are eligible to suspend nilotinib therapy by achieving and maintaining a sustained MR4.0 for at least 12 months during consolidation treatment with nilotinib 300 mg BID [Time Frame: 12 months] - The kinetics of the molecular response in patients during induction/consolidation treatment with nilotinib 300 mg BID. [Time Frame: 24 or 36 months depending on randomized arm] - The kinetics of the molecular response in patients during the TFR phase of the study in the two treatment arms. [Time Frame: 36months (arm1); 24 months (arm2)] - Progression-free survival (PFS) rate during the TFR phase of the study. [Time Frame: 36 months (arm1); 24 months (arm2)] - Treatment -free survival (TFS) during the TFR phase of the study [Time Frame: 36 months (arm1); 24 months (arm 2)] - Overall survival (OS) rate during of the TFR phase of the study. [Time Frame: 36 months (arm1); 24 months (arm2)] - Safety profile of nilotinib during the induction/consolidation treatment phase, the TFR phase, and during the treatment re-initiation phase. [Time Frame: 60 months]
Inclusion Criteria	- Confirmed diagnosis of chronic phase Ph+ CML - Previous first-line treatment with imatinib for a minimum of 2 years - Patient in complete cytogenetic response;
Exclusion Criteria	- Previous achievement of MR4.0 at study entry; - Previous treatment with other target cells inhibitors other than imatinib; - Patients with any history of detectable atypical Leukemia transcripts or patients with detectable atypical leukemia transcripts at screening; - Previous anticancer agents for Chronic myeloid leukemia other than imatinib except for cytoreduction; - Severe and/or uncontrolled concurrent medical disease that in the opinion of the investigator could cause unacceptable safety risks or compromise compliance with the protocol; - History of other active malignancies within the 5 years prior to study entry with the exception of previous or concomitant basal cell skin cancer and previous carcinoma in situ treated curatively; - Patients who have not recovered from prior surgery;

- Treatment with other investigational agents within 4 weeks of Day 1;
- Impairment of gastrointestinal (GI) function or GI disease that may significantly alter the absorption of study drug;

Age	>= 18 years
Status	No longer recruiting
start of Recruitment	01.04.2013
Recruiting countries	Germany France Czech Republic Belgium Spain Italy Portugal Bulgaria Slovakia Austria Norway Ireland Hungary Finland Denmark Sweden
Target Sample Size	1058
Leader	Saußele, Prof. Dr. med., Susanne Universitätsmedizin Mannheim III. Medizinische Klinik Theodor-Kutzer-Ufer 1-3 68167 Mannheim Tel: +49 (0)621 383-6966 Fax: +49 (0)621 383-73 1500 Email: studien.haematologie@medma.uni-heidelberg.de
Sponsors	Novartis Pharma AG (Main Sponsor)
Supporters	Novartis Pharma AG Homepage: www.novartispharma.de/index.shtml
Other Registers	ClinicalTrials.govNCT01743989 European Clinical Trials Database - EUDRACT2012-005124-15