European LeukemiaNet
SHORTPROTOCOL
AMLSG 11-08

Public Title	Phase Ib/IIa Study For the Evaluation of Dasatinib Following Induction and Consolidation Therapy as well as in Maintenance Therapy in Patients With Newly Diagnosed Acute Myeloid Leukemia (AML
Scientific Title	Open-Label, Multicenter Phase Ib/IIa Study For the Evaluation of Dasatinib (Sprycel™) Following Induction and Consolidation Therapy as well as in Maintenance Therapy in Patients With Newly Diagnosed Core Binding Factor (CBF) Acute Myeloid Leukemia (AML
Short Title	AMLSG 11-08
Id KN/ELN	LN_AMLSGU_2009_314
Trialgoup	AMLSG Ulm
Type of Trial	multicentric, open-label
Phase	Phase I/II
Disease	Acute myeloid leukemia(AML) AML all subtypes without FAB M3
Stage of Disease	de novo/non-treated - Therapy concepts for specific genotypes - All age groups
Aim	- To assess the feasibility of dasatinib 100 mg QD given after intensive induction (daunorubicin and cytarabine) and consolidation chemotherapy (high-dose cytarabine) and as single agent in maintenance therapy - To assess survival endpoints such as cumulative incidence of relapse (CIR) and death (CID), and overall survival (OS
Outcomes	- Rate of early/hypoplastic death (Rate(ED/HD))<10% - Rate of pleural or pericardial effusion grade 3/4 (Rate(effuse))<10% - Rate of liver toxicity grade 3 or 4 that does not improve to grade 2 or less within 14 days after discontinuing responsible medication (Rate(liver))<10% - Rate of refractory disease (Rate(RD))<10% - Cumulative incidence of relapse (CIR) and death CID) - Overall survival (OS)
Inclusion Criteria	- Core binding factor (CBF) AML with molecular diagnosis of RUNX1-RUNX1T1 fusion transcript resulting from t(8;21)(q22;q22) (or a variant form) or of CBFB-MYH11 fusion transcript resulting from inv(16)(p13.1q22)/t(16;16)(p13.1;q22) as assessed in one of the central AMLSG reference laboratories - Age 18; there is no upper age limit - No prior chemotherapy for leukemia except hydroxyurea for up to 5 days during the diagnostic screening phase - Non-pregnant and non-nursing. Due to the unknown teratogenic potential of dasatinib in humans, pregnant or nursing patients may not be enrolled. Women of childbearing potential (WOCBP) must have a negative serum or urine pregnancy test within a sensitivity of at least 25 mIU/mL within 72 hours prior to registration. Women of child-bearing potential must either commit to continued abstinence from heterosexual intercourse or begin TWO acceptable methods of birth control - one highly effective method (e.g., IUD, hormonal, tubal ligation, or partner's vasectomy), and one additional effective method (e.g., latex condom, diaphragm, or cervical cap) - AT THE SAME TIME, at least four weeks before she begins dasatinib therapy. "Women of childbearing potential" is defined as a sexually active mature woman who has not undergone a hysterectomy or who has had menses at any time in the preceding 24 consecutive months - Men must agree not to father a child and must use a latex condom during any sexual contact with women of childbearing potential while taking dasatinib and for 4 weeks after therapy is stopped, even if they have undergone a successful vasectomy - Signed written informed consent
Exclusion Criteria	- Performance status WHO >2

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- Pulmonary edema and/or pleural/pericardial effusion within 14 days of Day 1. If edema/effusion resolves to CTC Grade 1, patients can be treated with dasatinib
- Patients with ejection fraction < 50% by echocardiography within 14 days of day 1
- Organ insufficiency (creatinine >1.5x upper normal serum level; bilirubin, AST or AP >2.5x upper normal serum level; heart failure NYHA III/IV; severe obstructive or restrictive ventilation disorder)
- Severe neurological or psychiatric disorder interfering with ability of giving an informed consent
- Known positive for HIV
- Bleeding disorder independent of leukemia
- No consent for registration, storage and processing of the individual disease-characteristics and course as well as information of the family physician about study participation

Age >= 18 years

Status Closed

start of Recruitment 03.09.2009

Recruiting countries Germany

Austria

Target Sample Size 82

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Supporters	Bristol-Myers Squibb
Other Registers	ClinicalTrials.govNCT00850382 (Primary Register)