

## Ongoing studies in the ELTR (European Leukemia Trial Registry)

The European Leukemia Trial Registry - ELTR ([www.leukemia-trials.eu](http://www.leukemia-trials.eu)) is the first international registry dedicated specifically to leukemia trials. Currently, over 70 active European leukemia studies are listed, including investigator-initiated trials administered by study groups of the ELN or trials initiated by pharmaceutical companies and conducted in several European countries. Detailed study information and short-protocols are available for free download on the website. German national trials are listed in the German Leukemia Trial Registry at [www.studienregister-online.de](http://www.studienregister-online.de).

[www.leukemia](http://www.leukemia)

We are aware of the fact that the represented trials only reflect a part of the real study volume in Europe. This is mainly due to an incomplete announcement of newly enrolled trials to the ELTR. The ambitious goal to give a complete overview about the local and European trials on leukemia can only be achieved by joint support and continuous promotion of the ELTR by all study groups. In this matter, we would like to encourage everybody to register their new and update their listed trials. For more information please contact the European Leukemia Information Center ELIC ([elic@em.uni-frankfurt.de](mailto:elic@em.uni-frankfurt.de)).

### Acute lymphoblastic leukemia

#### All subtypes

- B1371001 - A Study Of PF-04449913 In Select Hematologic Malignancies
- GALL - Genotyping Analysis of Acute Lymphoblastic Leukemia

#### de novo/non-treated

- GRAALL 02/2005 - Treatment of Acute Lymphoblastic Leukemia (ALL) in Younger Adults
- ALL -SCT Ph negative - Role of autologous bone marrow transplantation plus maintenance therapy in adult ALL
- LAL-AR/2003 - Therapy of high-risk ALL
- NILG-ALL 10/07 - Intrathecal DepoCyte and Lineage-targeted MRD-oriented Therapy of ALL
- UKALL 14 - Standard Chemotherapy With or Without Nelarabine or Rituximab in Newly Diagnosed ALL

#### B-Precursor ALL

##### de novo/non-treated

- ALL GRAALL 02/2005-R - Mabthera + induction, consolidation and late intensification in Ph neg., CD20+ ALL

##### molecular relapse

- MT103-203 - Confirmatory Phase II Study of Blinatumomab (MT103) in Patients With MRD of B-precursor ALL (BLAST)

##### relapsed/refractory

- MT103-211 - Phase II Trial with Blinatumomab in relapsed/refractory B-precursor ALL
- MARALL - Monoclonal Antibodies in Recurrent or Refractory B Cell ALL

#### Ph/BCR ABL +

##### de novo/non-treated

- ALL GRAAPH 02/2005 - Imatinib-based vs. standard imatinib containing Hyper CVAD induction in de novo Ph+ ALL
- GMALL-PH-01 - Study of standard induction and consolidation therapy in combination with dasatinib in Ph+ ALL
- LAL1408 - Ph+/Bcr-Abl+ ALL Imatinib and Nilotinib Rotational Study

##### relapsed/refractory

- BMS CA 180 323 - Dasatinib Combo With SMO Inhibitor (BMS-833923)

#### non-B mature, non-Ph+ ALL

- GIMEMA LAL1308 - Combination Chemotherapy in Treating Young Adult Patients With ALL

#### Stem cell transplantation

- AlloSCT-Clofarabine - Allo-SCT With Clofarabine, Busulfan and Antithymocyte Globulin for High-Risk AML, MDS or ALL

### Acute myeloid leukemia

#### AML all subtypes without FAB M3

- AML-NILG 02/06 - Remission Induction Therapy and Risk-oriented Postremission Strategy for Adult AML
- B1371001 - A Study Of PF-04449913 In Select Hematologic Malignancies
- HOVON 103 AML Lenalidomide - Phase II Study to assess the tolerability and efficacy of oral lenalidomide to standard induction therapy
- HOVON 103 AML Tosedostat - Phase II Study to assess the tolerability and efficacy of oral tosedostat to standard induction therapy
- UHW-AML16 - Combination Chemotherapy With or Without GO or Tipifarnib in AML or High-Risk MDS

#### de novo/non-treated - Therapy concepts for all genotypes - All age groups

- CLBH589H2101 - Phase Ib study of Panobinostat and 5-Azacididine for MDS, CMML or AML

#### de novo/non-treated - Therapy concepts for all genotypes - >= 60 years

- GIMEMA AML1208 - Everolimus MICE-regimen in Treating Older Patients With Newly Diagnosed AML
- GIMEMA AML19 - GO in Treating Older Patients With Previously Untreated AML
- HOVON 97 AML - Maintenance therapy with Azacitidine in elderly AML and refractory anemia with excess of blasts (RAEB, RAEB-T)
- Intergroup Elderly - AML Intergroup - joint study arm in patients from 60 years
- SPARK-AML1 - AZD1152 Alone and in Combination With LDAC in Comparison With LDAC Alone in de novo AML

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### de novo/non-treated - Therapy concepts for specific genotypes - < 60 years

- P060504 - Timed-Sequential Induction in CBF-AML

### de novo/non-treated - Therapy concepts for specific genotypes - All age groups

- AMLSG 09-09 - Phase III study of chemotherapy in combination with ATRA with or without gemtuzumab ozogamicin in patients with acute myeloid leukemia and NPM1 gene mutation
- AMLSG 16-10 - Protocol in Acute Myeloid Leukemia With FLT3-ITD

### de novo/non-treated - Not specified - < 60 years

- AML ALFA-0702 - The CLARA Study from the Acute Leukemia French Association
- LAM20061R - Efficacy of Gemtuzumab Ozogamycin for AML With Intermediate Risk
- MDS Clofarabine - Clofarabine, Cytarabine, and Idarubicin in Intermediate-Risk or High-Risk AML or High-Risk MDS

### de novo/non-treated - Not specified - >= 60 years

- AZA-AML-001 - Study of Vidaza Versus Conventional Care Regimens for the Treatment of AML

### de novo/non-treated - Not specified - All age groups

- AML MEK - Trial of Mitogen-activated Protein/Extracellular Signal-regulated Kinase Kinase (MEK) Inhibitor

### relapsed/refractory

- MEK 111759 - Phase I/II Study on the MEK Inhibitor GSK1120212 in rel./ref. Leukemias

### FAB M3 (APL)

- B1371001 - A Study Of PF-04449913 In Select Hematologic Malignancies

### de novo/non-treated

- APL 04-06 - Combination Chemotherapy in Treating Patients With Newly Diagnosed APL
- P050604 - Acute Promyelocytic Leukemia 2006 (APL)

### relapsed/refractory

- PROMYSE - A pan-European registry for relapsed APL patients

### Stem cell transplantation

- AlloSCT-Clofarabine - Allo-SCT With Clofarabine, Busulfan and Antithymocyte Globulin for High-Risk AML, MDS or ALL
- HCT vs CT - HCT Versus CT in Elderly AML
- RICMAC - Dose-Reduced Versus Standard Conditioning Prior Allo SCT for MDS/sAML

### Supportive study

- Eltrombopag - Eltrombopag in MDS and AML with Thrombocytopenia

## Chronic lymphoblastic leukemia

### All stages

- TPLL2 - Combined Immunochemotherapy in Patients With T-Prolymphocytic Leukemia

### relapsed/refractory

- GIMEMA LLC0606 - Lenalidomide, Fludarabine, and Cyclophosphamide for Advanced Refractory CLL
- HOMB 114242 - Ofatumumab vs Physician's Choice in Subjects With Bulky Fludarabine-Refractory CLL

## Chronic myeloid leukemia

### All subtypes

- B1371001 - A Study Of PF-04449913 In Select Hematologic Malignancies

### Chronic Phase

- GIMEMA CML0408 - Nilotinib and Imatinib Mesylate in Treating Patients With Early CP-CML
- OPTIM DASATINIB - Phase II study to optimize the residual plasmatic level of dasatinib in chronic phase CML
- SPIRIT 2 - Comparison of Imatinib Versus Dasatinib in Newly-diagnosed CP-CML

### Imatinib resistance, -intolerance

- C AMN107 Y 2101 - Nilotinib and LDE225 in the Treatment of CML Patients Who Developed Resistance to Prior Therapy

### Complete molecular remission (MR4)

- EuroSKI - Stopping TKI in patients with CML in complete molecular remission (MR4)

### Intolerant/resistant to one TKI

- AMN2128 - Study of Nilotinib and Midazolam in CML Resistant and/or Intolerant Against One TKI
- BMS CA 180 323 - Dasatinib plus SMO-Inhibitor in CML and Ph+ ALL

## Myelodysplastic syndrome

### All subtypes

- B1371001 - A Study Of PF-04449913 In Selected Hematologic Malignancies

### Low risk and intermedia I

- EPOANE - An Efficacy Study for Epoetin Alfa in Anemic Patients With MDS
- EUMDS - European Registry for Low and Intermediate-1 MDS
- HOVON 89 MDS - A Phase II study of lenalidomide with or without erythropoietin and G-CSF in low and intermediate-1 risk MDS
- MDS Azacitidine-Epoetin Beta - Phase II study of Azacitidine and Epoetin Beta in low-risk and intermediate-1 MDS resistant to ESA
- MDS-005 - Lenalidomide Versus Placebo in Subjects With Transfusion Dependent Anemia in Low Risk MDS Without Del 5q
- MEK 111759 - Phase I/II Study on the MEK Inhibitor GSK1120212 in rel./ref. Leukemias
- SIMIDIS - Azacitidine and Beta Erythropoietin Treatment in Patients With MDS Red Cell Transfusion Dependent

### Intermedia II and high risk

- AML MEK - Trial of Mitogen-activated Protein/Extracellular Signal-regulated Kinase Kinase (MEK) Inhibitor
- AML-NILG 02/06 - Remission Induction Therapy and Risk-oriented Postremission Strategy for Adult AML
- Eltrombopag - Eltrombopag in MDS and AML with Thrombocytopenia
- HOVON 97 AML - Maintenance therapy with Azacitidine in elderly AML and RAEB/RAEB-T
- HOVON 103 AML Lenalidomide - Phase II Study to assess the tolerability and efficacy of oral lenalidomide to standard induction therapy
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- MDS Clofarabine - Clofarabine, Cytarabine, and Idarubicin in Intermediate-Risk or High-Risk AML or High-Risk MDS
- MDS Erlotinib - Erlotinib in Higher Risk MDS
- MDS Velcade Zarnestra - Bortezomib and Tipifarnib in MDS
- MEK 111759 - Phase I/II Study on the MEK Inhibitor GSK1120212 in rel./ref. Leukemias
- ONO 1910 - Randomized Study of ON 01910.Na in Refractory MDS With Excess Blasts
- QOL II - Quality of Life and Symptoms in Patients With Newly Diagnosed MDS
- UHW-AML16 - Combination Chemotherapy With or Without GO or Tipifarnib in AML or High-Risk MDS

### Stem cell transplantation

- AlloSCT-Clofarabine - Allo-SCT With Clofarabine, Busulfan and Antithymocyte Globulin for High-Risk AML, MDS or ALL
- RICMAC - Dose-Reduced Versus Standard Conditioning Prior Allo SCT for MDS/sAML

## Myeloproliferative disease

### All subtypes

- B1371001 - A Study Of PF-04449913 In Select Hematologic Malignancies

### Essential Thrombocythaemia

- ARD12042 - Study With SAR302503 in Patients With Polycythemia Vera or Essential Thrombocythemia

### Myelofibrosis

- JAKARTA - Phase III Study of SAR302503 in Intermediate-2 and High Risk Patients With Myelofibrosis
- JUMP - Expanded access study of INC 424 for PMF, PPV MF or PET-MF
- RESUME - Study of Pomalidomide in MPD-Associated Myelofibrosis with RBC-Transfusion-Dependence

### Polycythaemia vera

- ARD12042 - Study With SAR302503 in Patients With Polycythemia Vera or Essential Thrombocythemia
- RESPONSE - Study of INC424 in PV with Resistance to or Intolerance of Hydroxyurea

## Stem cell transplantation

- 152/2008/U/Sper - Intrabone Infusion of Cord Blood Hemopoietic Stem Cells in Adult Patients With High Risk Haematological Malignancies

## Supportive care

- BUM-5/GVH - Efficacy and Safety Study of Budesonide to Treat Oral Chronic GvHD
- Isavuconazole WSA-CS-004 - Isavuconazole for Primary Treatment of Invasive Aspergillosis