

Dear members of the ELN,

with the new online-database for suspected-adverse-drug-reactions side-effect-reporting becomes open to the public. With the launch of this website in May 2012 the European Medicines Agency underlines the importance of transparent pharmacovigilance in Europe. For more information on this database, on the updated Czech CML patient information, and current topics from the network please have a look below.

We hope you will enjoy reading.

Kind regards,

European Leukemia Information Center - ELIC

### ■ **Public database of suspected adverse drug reaction reports**

Recently, the European Medicines Agency launched a new website publishing suspected side-effect reports which are fed in electronically from the EudraVigilance database. Reports are available for all medicines authorized in the European Economic Area. ▶ [more information on the new database](#)

### ■ **Czech brochure for CML-patients and their relatives**

The Czech Leukemia Study Group for Life (CELL) published the Czech CML patient information 'Chronická Myeloidní Leukemie - Informace pro pacienty a jejich blízké'. The brochure by Daniela Žáčková can be downloaded for free on the ELN website. ▶ [brochure for free download and ordering information](#)

### ■ **Update of WP participants**

On a half-yearly basis the contact data of active WP participants are updated on the website. The current lists as well as short overviews of the respective lead participants are online now. Please find these lists including the participant's organization, nationality and e-mail address in the section "contact" of every workpackage. ▶ [contact NMC for changes](#)

### ■ **ELN Breakfast Meeting at the ASH 2012**

This year's 54<sup>th</sup> ASH Annual Meeting and Exposition takes place from December 8-11 in Atlanta, USA. On Sunday December 9<sup>th</sup> the ELN will meet for the ELN breakfast meeting. The location and agenda of this meeting will soon be available on the website. ▶ [agenda of the ELN breakfast meeting](#)

### ■ **10<sup>th</sup> Annual Symposium of the European LeukemiaNet**

On February 5-6 2013, the Annual Symposium of the European LeukemiaNet together with the 14<sup>th</sup> Annual Symposium of the German Competence Network 'Acute and chronic Leukemias' will take place in Mannheim. From November, the program will be provided on the website. ▶ [detailed information on the 10<sup>th</sup> Annual Symposium](#)

### ■ **Publications from the Network (selected)**

- ▶ Burnett AK et al., The addition of the farnesyl transferase inhibitor, tipifarnib, to low dose cytarabine does not improve outcome for older patients with AML. Br J Haematol. 2012 Aug;158(4):519-22.
- ▶ Cornelissen JJ et al., The European LeukemiaNet AML Working Party consensus statement on allogeneic

HSCT for patients with AML in remission: an integrated-risk adapted approach. *Nat Rev Clin Oncol*. 2012 Sep 4;9(10):579-90.

- ▶ Della Porta MG et al., Multicenter validation of a reproducible flow cytometric score for the diagnosis of low-grade myelodysplastic syndromes: results of a European LeukemiaNET study. *Haematologica*. 2012 Aug;97(8):1209-17.
- ▶ Gökbuget N et al., Outcome of relapsed adult lymphoblastic leukemia depends on response to salvage chemotherapy, prognostic factors, and performance of stem cell transplantation. *Blood*. 2012 Sep 6;120(10):2032-2041.
- ▶ Metzeler KH et al., High expression of lymphoid enhancer-binding factor-1 (LEF1) is a novel favorable prognostic factor in cytogenetically normal acute myeloid leukemia. *Blood*. 2012 Sep 6;120(10):2118-26.
- ▶ Moorman AV et al., IGH@ Translocations, CRLF2 Deregulation, and Microdeletions in Adolescents and Adults With Acute Lymphoblastic Leukemia. *J Clin Oncol*. 2012 Sep 1;30(25):3100-8.
- ▶ Passamonti F et al., A prognostic model to predict survival in 867 World Health Organization-defined essential thrombocythemia at diagnosis: a study by the International Working Group on Myelofibrosis Research and Treatment. *Blood*. 2012 Aug 9;120(6):1197-201.

## ■ New trials in the ELTR

**ARD12042** A Randomized Phase II, Open-Label Study of the Efficacy and Safety of Orally Administered SAR302503 in Patients With Polycythemia Vera (PV) or Essential Thrombocythemia (ET) Who Are Resistant or Intolerant to Hydroxyurea

**BUM-5/GVH** Double-blind, Randomised, Placebo-controlled Multicentre Phase III Clinical Study Followed by Open-label Phase on the Efficacy and Tolerability of Budesonide 3 mg Effervescent Tablet in Patients With Resistant Oral Chronic GvHD

**C AMN107 Y 2101** A Single-arm Dose-finding Phase Ib Multicenter Study of the Oral Smoothened Antagonist LDE225 in Combination With Nilotinib in Chronic Phase Chronic Myeloid Leukemia Patients Who Have Failed Prior Therapy With Other BCR-ABL Tyrosine-kinase Inhibitors

**JAKARTA** A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, 3-Arm Study of SAR302503 in Patients with Intermediate-2 or High-Risk Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, or Post-Essential Thrombocythemia Myelofibrosis with Splenomegaly

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### ■ ■ European Leukemia Information Center - ELIC

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