

## Dear colleagues and study teams,

We just registered the 700<sup>th</sup> patient and would like to thank all active sites for their collaboration. As communicated before, the recruitment for CLLM1 is far from the expected randomized 200 patients – to date, 67 pts have been randomized.

We are facing the dramatic changes in CLL treatment with the approval for Ibrutinib and Idelalisib. In particular for patients with high risk CLL these new options are available.

In addition, patients do have objections against maintenance strategies. Unfortunately, we saw many patients who withdrew their consent after firstline treatment and cancel continuation with CLLM1. To ensure the analysis of the role and value of maintenance with Lenalidomide we now aim to randomize as many patients as possible.

**Recruitment will be continued until end of the year 2015 at least, but immediately we will stop the entire pre-screening procedures. This means from now on patients can only be registered after firstline treatment. For screening MRD analysis only will be performed.**

### 3<sup>rd</sup> Amendment of CLLM1-Protocol

The 3<sup>rd</sup> Amendment of the study protocol is now in preparation, will be submitted soon and following the approval you will receive all relevant documents.

Please note:

- From now on, pre-screening procedures are no longer included in the CLLM1 protocol. Thus, no blood samples with the exception of MRD assessment after firstline will be drawn, shipped and analyzed for the study.
- Recruitment is still open for eligible patients: This includes all patients who underwent pre-screening so far. In addition you are allowed to screen any eligible patients, if they can be stratified according to the protocol. Any results from local labs are allowed.

In this context the patient informed consent forms were adapted as well.

### New versions of screening CRF and transmittal form

Please take notice that CRF was adapted to Amendment 2. The new Screening CRF version 4.0 (Page 1 – 16) contains the following changes:

- Page 2: Point 8 & 14 → Update Inclusion/ Exclusion Criteria
- Page 4: Point 12 → new item “Date of initial diagnosis of CLL” was included
- Page 6: Point 7 & 12 → Update Inclusion Criteria
- Page 7: Point 11 → Update Exclusion Criteria

We kindly ask to replace the old version 3.0 and to use from now on the new version 4.0

For all patients using the version 3.0 since last amendment we will send out a query.

A new transmittal form version 2.0 is available and should be used from now on.

All documents are ready for download from the password-protected download area (<http://www.dcllsg.de/dcllsglogin/cllm1/index.php>) of our web page: [www.dcllsg.de](http://www.dcllsg.de)

### Top Recruiter

Active sites and number of recruited-patients	Pat
Universitätsklinik Köln	4
Gemeinschaftspraxis Drs. Aldaoud/ Schwarzer, Leipzig, Onkologische Gemeinschaftspraxis Dres. Dörfel/ Göhler, Dresden	3
Universitätsklinikum Essen, Universitätskliniken des Saarlandes, Universitätsklinikum Magdeburg A.ö.R., Stauferklinikum Schwäbisch-Gmünd, Klinikum Ernst von Bergmann, Potsdam, Gemeinschaftspraxis Schick/Schick/Schmidt/Wiesmeier, München, Internistische Gemeinschaftspraxis Dres. Ule/ Müller/ Kröning/ Jentsch-Ullrich, Magdeburg, Internistische Gemeinschaftspraxis Prof.Knauf/ Tesch am KH Bethanien, Frankfurt, Onkologische Schwerpunktpraxis Darmstadt, Hanusch-Krankenhaus, Wien, Österreich, Hospital Univ. 12 de Octubre, Spain	2
Universitätsklinikum Schleswig-Holstein Campus Kiel, Helios-Klinikum Erfurt, Universitätsklinik Ulm, RWTH Aachen, Evang. Krankenhaus Hamm, Klinikum Idar-Oberstein GmbH, Paul-Gerhardt-Stift, Lutherstadt Wittenberg, Krankenhaus der Barmherzigen Brüder, Regensburg, Hämatologische/ onkologische Gem.-Praxis Dres. Brudler/ Heinrich/Bangerter, Augsburg, Onkologische Gemeinschaftspraxis Dres. Bojko/ Abenhardt/ Bosse, München, Hämatologie und Internistische Onkologie Dres. Nüchel/ Bückner, Bochum, Dres. Siehl/ Söling, Fachärzte für Hämatologie und Internistische Onkologie, Kassel, Internistische Gemeinschaftspraxis Dres. Günther/ Sauer, Potsdam, Praxisklinik für Hämatologie und Onkologie Koblenz, Internistische Gemeinschaftspraxis Dres. Schmitz/ Steinmetz, Köln, Internistische Praxis Dr. Scherpe, Stade, Internistische Gemeinschaftspraxis Dres. Balló/ Böck, Offenbach, MediProjekt GBR, Internistische Gemeinschaftspraxis Dres. Kamp/ Eckert, Wendlingen, Onkologische Gemeinschaftspraxis Dr. M. Neise u. Dr. A. Lollert, Mannheim, Onkologie-Praxis, Onkologische Schwerpunktpraxis Dr. Müller, Leer, Sozialstiftung Bamberg, Schwerpunktpraxis Hämatologie/ Onkologie Celle, Hämatologische und Internistische Praxis Dr. Tessen, Goslar, Ospedale Oncologico Regionale Armando Businco, Ospedale S. Giovanni Battista - Le Molinette, Gemeinschaftspraxis Mohm/ Prange-Krex, Dresden, Ospedale Niguarda Ca'granda – Milano, Hospital Univ. Puerta de Hierro – Majadahonda, Hospital del Mar – Barcelona, Ospedale Ferrarotto, Academisch Medisch Centrum, Amsterdam, Hegau Bodensee Klinikum	1

**Please contact us**, if you have any questions around CLLM1 study, we are happy to discuss every patient or question with you. DCLLSG study office: +49 221-478-88220

Yours sincerely

PD. Dr. med. Barbara Eichhorst  
CPI Germany

Dr. med. Anna Fink  
Coordinating physician