NORDIC CANCER UNION

# Report NCU grant

Report submission date: 01.03.2013

Main applicant: Peter de Nully Brown

Project title: Nordic Lymphoma Group: A Nordic collaboration to combat malignant lymphoma.

NCU grant received (€): 40 000

Project commencement and completion dates: For the year 2012. Grants given for several years previously

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## 1. Brief description of the project, written in a language understandable to non-scientists (Maximum length: 100 words)

The goals of the Nordic Lymphoma Group (NLG), to conduct research into the biology, epidemiology and treatment of malignant lymphoma in the Nordic countries, have been pursued during 2011 – 2012 by the accrual to the NLG's portfolio of new interventional and translational research protocols. Several large and innovative clinical studies have been closed, published or awaited for final analysis and publications during 2013. Large cell lymphoma group CRY04-study is published in Annals of Oncology 2013, mantle cell lymphoma group (MCLIII-study) manuscript is in preparation and T-cell lymphoma group NLG-T-01 study was published in Journal of Clinical Oncology 2012. These studies are being replaced by a new trial generation developed by the respective working groups as detailed below.

## 2. Summarize the major findings of the project (Maximum length: 400 words)

Hodgkin Lymphoma

- The Hodgkin group has presented an abstract in the lymphoma meeting in Lugano, June 2011, on the results of the Nordic study of low and intermediate stages of Hodgkin lymphoma. A manuscript is in preparation
- Sweden, Norway and Denmark have joined an international study, RATHL, on advanced Hodgkin lymphoma focusing on the treatment adjustment according to early metabolic response measured by PET. Accrual to RATHL study is closed as scheduled and results are awaited. An abstract for Lugano 2013 will be submitted.

- New chairman Dr Alexander Fosså presented new protocol suggestion in December 2011 for treatment of elderly patients with Hodgkin lymphoma. The revised protocol is still under concideration by the company involved.
- Sweden, Norway and Denmark are planning to join the German HD 16 trial.
- The Hodgkin group was not allocated support from NCU for 2011.

Large cell lymphoma:

- CRY-04 study: Final analysis with the median follow-up of more than three years has been performed, and the manuscript on clinical data was published in Annals of Oncology (Holte et al., 2013). Several correlative studies on the basis of CRY-04 biological material have also been initiated. A study on a prognostic impact of serum VEGF levels on the survival of the patients treated in the CRY-04 study has been published in EJH (Riihijärvi et al., 2012),and study on the array comparative genomic hybridizations (aCGH) and exon-based transcriptome profiling submitted for publication. Additional molecular substudies including analysis of alternative splicing events and their association on survival, exome and RNA sequencing, tissue microarrays, and multiplex ELISAs from plasma are ongoing.
- The PET study has included the planned 100 patients and the final analysis of the data has been completed in October 2012. The study group is working on the manuscript.
- CHIC study: A new phase II follow-up study for the CRY-04 protocol was finalized on December 2010, and is opened for recruitment in all Nordic countries on March 2011. The purpose is to test whether early CNS prophylaxis given at the beginning of therapy for young high-risk DLBCL patients is feasible and could reduce the risk of CNS relapses. About 60 patients are recruited so far. The first interim analysis on safety was performed on October 2012 after 40 patients had completed the treatment. The results showed reasonable toxicity and satisfactory response rates and it was recommended to continue the study. The results of the interim analyses will be presented at the Lugano meeting in June 2013. The study will be open for additional three years. Material for correlative biological studies is collected (tumor tissue, blood and cerebrospinal fluid).

The fraction of the NCU grant 2011 allocated by the coordination group to the activities of the large cell group has been used for (i) statistics, (ii) meeting activities, (iii) laboratory reagents.

Indolent (low-grade Lymphoma:

- The second protocol on Rituximab + INF-$\alpha$ in low-grade NHL has been completed and the final analysis is ready. An abstract was presented orally in the Lugano meeting 2011 and a manuscript will be published 2013.
- The database for the two rituximab trials are now in Copenhagen in the ownership of NLG, and further analysis of the data is ongoing. Several spin-off projects are ongoing: e.g. mRNA expression array with fresh-frozen tissue in collaboration with Andreas Rosenwald's laboratory. The data will be related to clinical data
  An open label Follow-up study to M39035 and ML16865, to evaluate the Long-term efficacy and post-treatment effects of rituximab administered as single agent or in combination with Interferon-a2a (Roferon-A®), is planned.
- A meta-analysis intended to qualify durable CR as a surrogate endpoint for PFS in first-line FL will be conducted in collaboration with Prof. Daniel Sargent from the Mayo clinic with input from a Scientific Advisory Committee, the FLASH (Follicular Lymphoma Analysis of Surrogacy Hypothesis) Group) in which Eva Kimby is the representatives from NLG.
- *NLG-SAKK follicular protol:* A randomised phase 2 study in collaboration with Swiss lymphoma group on upfront treatment for follicular lymphoma is ongoing in Norway, Sweden, Denmark and Finland and has recruited more 2/3 of the patients. The protocol treatment is 4+4 rituximab with or without

lenalidomide. Fresh-frozen tissue and cells have been saved and translational research studies are planned.

- *A new trial is planned together with the SAKK group.*

The NCU grant has been spent on molecular and immunohistochemical analysis of the two protocols on Rituximab +/- INF-α and meeting activities.

Mantle cell lymphoma:

- MCLII protocol: In addition to the manuscript published in Blood 2008, another two manuscripts have been published, one on minimal residual disease and one on predictive factors for response and survival. An update of the MCL2 study has been published in British Journal of Hematology 2012 (Geisler et al).
- The MCLII is succeeded by the MCLIII. The results of MCLIII study were presented orally at the ASH meeting Dec. 2012 and will be submitted for publication soon.
- The B-cell receptor characteristics of the Nordic MCL2 and MCL3 patients have been included in a large European collaborative analysis of BCR stereotype in MCL (Hadzimitriou et al 2011).
- A new phase I / II study on frontline therapy in elderly patients is open in the Nordic countries (MCL IV Lena-BeRit; bendamustin, rituximab, lenalidomide with a dose finding study of lenalidomide as the phase I part of the study). The study is recruiting well. Phase I has been concluded and presented in ASH 2011. Phase II is recruiting is planned to be concluded in 2013.
- A new study for high risk patients with mantle cell lymphoma was closed prematurely due to inadequate treatment results (MARIT study, core of treatment schedule is high dose cytarabine combined with rituximab and autologous stem cell transplantation consolidation) and new protocol is in preparation.
- Several biological studies are planned on both ongoing studies with special emphasis on molecular response evaluation.

NCU grant was spent on detection of minimal residual disease.

T-cell lymphoma:

- The T-01 study: After the publication of the German experience pointing at the occurrence of late relapses in T-cell lymphomas, a decision was taken to publish the final analysis of the NLG-T-01 study with a 5-year median follow-up time (data presented at the EHA 2009 with 3½ year median follow-up and at ASH 2011 with a 5 year median follow-up). The analysis results were elaborated by the NLG statistician Harald Anderson, Dept. of Oncology, Lund University Hospital. The manuscript with the final analysis of the study was published in the Journal of Clinical Oncology in 2012.
- An abstract with a subset analysis of angioimmunoblastic TCL has been presented in the Lugano 2011 meeting (Lauritzsen G et al, June 2011). A similar subset analysis focusing on the subset of anaplastic large cell lymphomas was presented at ASH 2011 (Relander T et al, Dec 2011). Correlative biological studies on the basis of the NLG-T-01 tissue samples have been started.
- The T-02 protocol (ACT-1 trial): After a brief accrual pause (July 2009), accrual was resumed and has increased steadily. Moreover, since the introduction of the alemtuzumab dose reduction amendment. the number of adverse events has dropped dramatically. The ACT-1 trial has recruited approximately 100 patients and the ACT-2 100 patients. With a cumulative number of 200 pts, the ACT trial is already now the largest trial ever performed in systemic PTCL. Data on hematopoietic recovery after autologous stem cell reinfusion were presented at the Lugano 2011 and ASH meetings in 2011 and 2012.

The fraction of the NCU grant 2010 allocated by the coordinating group to the activities of the T-cell lymphoma group has been used for (i) meeting activities (clinicians and pathologists), (ii) statistics (UNI-C data management and conversion from the database to the NLG statistician) and (iii) submission fees for congress abstracts, (iv) laboratory reagents for immunohistochemistry and molecular biology.

CNS lymphoma:

CNS lymphoma protocol consists of a combined multiagent immunochemotherapy regimen based on HD-MTX and HD-Ara-C, intraspinal Depocyte and maintenance temozolomide therapy for responding elderly patients. The CNS lymphoma study was closed at the end of October 2010 after a successful accrual of 67 patients from 12 centers. The overall response rate (CR+PR) was 82.7%. Maintenance treatment was started in 15 of 27 elderly patients and is not completed for all patients as yet. The toxicity was mainly grade 3-4 infections occurring during neutropenia especially after HD-AraC. There were four treatment related deaths. CNS group is working on the manuscript which will be completed soon. CNS group is planning to join European CNS study protocol, discussions with Italian group on collaboration are ongoing.

Support distributed to the PCNSL group has been spent on data management, monitoring and submission fees for ASH meeting abstract.

Epidemiology group:

An observational study in chemotherapy regimens in adult Burkitt lymphoma has been performed, based on the Danish and Swedish lymphoma registry databases. Similar observational study in mantle cell lymphoma is initiated and will be concluded during 2012.

Epidemiology group was not allocated support from NCU for 2011.

## 3. Describe how the project has increased our knowledge of the prevention, cause and/or cure for cancer (Maximum length: 150 words)

Lymphoid cancer – malignant lymphoma - is the tenth most frequent cancer in the Nordic countries, amounting to a total of 5000 cases annually. Malignant lymphoma, however, comprise many subentities, which in the WHO classification amounts to more than 20 different diseases, each with its own particular malignant phenotype, biology, and treatment option.

The Nordic Lymphoma Group has gained considerable insight into the planning and management of clinical studies with translational research aspects. The ”harvest” in terms of new insight when running clinical studies is based on hard work over several years.

Among the major achievements of NLG during the last years are i) results from Mantle cell lymphoma protocol II which by many throughout the world is considered standard therapy today, ii) preliminary results from Hodgkin lymphoma trial for limited stage disease with the use of smaller radiation fields with lower doses resulting in less long term side effects while maintaining excellent survival and iii) results from two randomized first-line studies in indolent lymphomas showing excellent results with immunotherapy (antibody treatment with or without interferon) and iv) results from the T-cell lymphoma trial showing that induction chemotherapy with CHOEP-14 and autologous stem cell

transplantation is an effective treatment schedule for this lymphoma subtype, which earlier has not had any clear widely accepted treatment strategy.

4. Outline how Nordic cooperation has added value to this project (Maximum length 100 words)

The number of cases diagnosed annually countrywise within each subtype is often too small to allow the conduct of medium-large size clinical trials. In order to gain increased knowledge, particularly at subtype level, large, homogeneously treated patient cohorts with a possibility for long-term follow-up are needed.

The Nordic collaboration provided by the NLG framework enables us to recruit patient cohorts of sufficient size , to study lymphoma subtypes clinically and molecularly, and to follow them prospectively in order to gain clinically relevant new translational knowledge. Also, the Nordic group contributes substantially with patient accrual into collaborative European randomised trials.

5. Publications resulting from this and previous grants

NORDIC LYMPHOMA GROUP LIST OF PUBLICATIONS 2007– :

1. Björkholm M, Hagberg H, Holte H, Kvaloy S, Teerenhovi L, Anderson H,Cavallin-Ståhl E, Myhre J, Pertovaara H, Ost A, Nilsson B, Osby E. Central nervous system occurrence in elderly patients with aggressive lymphoma and a long-term follow-up. Ann Oncol 2007 Jun;18(6):1085-9.
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3. Geisler CH, Kolstad A, Laurell A, Andersen NS, Pedersen LB, Jerkeman M, Eriksson M, Nordstrom M, Kimby E, Boesen AM, Kuittinen O, Lauritzsen GF, Nilsson-Ehle H, Ralfkiaer E, Akerman M, Ehinger M, Sundstrom C, Langholm R, Delabie J,Karjalainen-Lindsberg ML, Brown P, Elonen E. Long-term progression-free survival of mantle cell lymphoma following intensive front-line immunochemotherapy with in vivo-purged stem cell rescue: A non-randomized phase-II multicenter study by the Nordic Lymphoma Group. Blood 2008 2008;112:2687-93
4. Andersen NS, Pedersen LB, Laurell A, Elonen E, Kolstad A, Boesen AM, Pedersen LM, Lauritzen GF, Ekanger R, Nilsson-Ehle H, Nordström M, Fredén S, Jerkeman M, Eriksson M, Väärt J, Malmér B, Geisler CH for the Nordic Lymphoma Group. Preemptive treatment with rituximab of molecular relapse after autologous stem cell transplantation in mantle cell lymphoma. J Clin Oncol. 2009; 27: 4365-70.
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intensive 1st-line immunochemotherapy and autologous stem-cell transplantation (ASCT). Blood. 2010; 115: 1530-3.

6. van Oers MHJ, Tönnissen E, van Glabbeke M, Giurgia L, Jansen JH, Klasa R, Marcus RE, Wolf M, Kimby E, Vranovsky A, Holte H, Hagenbeek A, van der Reijden BA. BCL-2/IgH PCR status at the end of induction treatment is not predictive for progression free survival in relapse BAed/resistant follicular lymphoma: results of a prospective randomized EORTC 20981 phase III intergroup study. J Clin Oncol. 2010; 28: 2246-52.
7. van Oers MHJ, Van Glabbeke M, Giurgea L, Klasa R, Marcus RE, Wolf M, Kimby E, van t Veer M, Vranovsky A, Holte H, Hagenbeek A. Rituximab maintenance treatment of relapsed /resistant follicular non-Hodgkin's lymphoma: long-term outcome of the EORTC 20981 phase III randomized Intergroup study. J Clin Oncol. 2010; 28: 2853-8.
8. Linch DC, Yung L, Smith P, Maclennan K, Jack A, Hancock B, Cunningham D, Hoskin P, Qia W, Holte H, Boesen A-M, Grigg A, Browet AP, Treny M. Final analysis of the UKLG LY02 trial comparing 6 - 8 cycles of CHOP with 3 cycles of CHOP followed by a BEAM autograft in patients <65 years with poor prognosis histologically aggressive NHL. Br J Hematol 2010;149:237-43.
9. Geisler C, Kolstad A, Laurell A, Räty R: Mantle cell lymphoma .- does primary intensive immunochemotherapy improve overall survival in younger patients? Leuk Lymphoma. 2009 Jun 26:1-8. (Invited paper).
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Kimby E. Management of Stage IV Peripheral T-Cell Lymphomas. Current Hematologic Malignancy Reports. 2007;2: 242-248.
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14. Björn Engelbrekt Wahlin, Christer Sundström, Harald Holte, Hans Hagberg, Martin Erlanson, Herman Nilsson-Ehle, Ola Lindén, Marie Nordström, Bjørn Østenstad, Christian H. Geisler, Peter de Nully Brown, Tuula Lehtinen, Martin Maisenhölder, Anne M. Tierens, Birgitta Sander, Birger Christensson, and Eva Kimby.T cells in tumors and blood predict outcome in follicular lymphoma treated with rituximab. Clin Cancer Res 2011;17:4136-44.
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21. Vase, Maja Ølholm; Friis, S; Bautz, A; Bendix, Knud; Sørensen, Henrik Toft; D'Amore, Francesco Annibale. Breast implants and anaplastic large cell lymphoma: A Danish population-based cohort study. J Nat Cancer Inst, 2013 (in press)
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