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European Leukaemia Network is announcing long term collaboration with Novartis to improve understanding and treatment of Chronic Myeloid Leukemia

University of Heidelberg, Germany: The European LeukemiaNet (ELN) and Novartis today launched a collaboration committed to improving understanding and treatment of chronic myeloid leukemia (CML). The collaboration was initiated by the signing of a Scientific Collaboration Agreement between the University of Heidelberg, Germany, and Novartis, Switzerland. The University of Heidelberg is acting for and on behalf of the CML-Members of the ELN and Professor Rüdiger Hehlmann represented the ELN

Uniting the expertise of the ELN and Novartis, the objectives of the collaboration are to gain a real-world pan-European picture of the incidence, distribution and control of CML and to inform and encourage improved management of the disease amongst healthcare professionals. These aims will be achieved by encouraging uptake of guidelines for the treatment of CML issued by the ELN in 2006¹ and by investigating the effects of treatments in patients across Europe.

“The European LeukemiaNet is committed to conducting clinical research and providing guidance to healthcare professionals about all types of leukemia, and CML is a key priority for us,” commented Professor Hehlmann, Coordinator of the ELN. “We are delighted to partner with Novartis, a company with a strong heritage in this field, to undertake a number of pan-European initiatives which will not only define best practice in the monitoring of CML patients but will deliver important advances in the understanding and treatment of this serious disease.”

A key activity to be undertaken during the collaboration is the extension of the ELN's registry of patients – a database which follows CML patients and provides a real world picture of their treatment and its outcomes – into a pan-European study. This important initiative will provide a clear picture of the current management of CML and will inform future guidance provided to physicians by the ELN.

The parties will also expand the availability of monitoring services available to physicians treating patients with CML, providing free access to state of the art technology which can assess patients' response to treatment, and thus help healthcare professionals in identifying when a different treatment might be needed. A further initiative will gather a large bank of data

to enable the assessment of the most effective doses of the small molecule targeted therapy imatinib (Glivec), a key treatment option in the management of CML.

“Novartis is pleased to unite with the ELN in a collaboration which will take existing state of the art clinical programs and turn them into beacons of best practice in the management of CML. We look forward to working with the ELN to implement these initiatives and to the impact they will have on the management of CML,” concluded Guido Guidi, Head Region Europe Novartis Oncology, Novartis.

This Collaboration is funded by Novartis

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Notes to editors

About the Alliance

The objectives of the ELN Alliance with Novartis are to:

- Increase understanding of the epidemiology of CML, its treatment and real life patient outcomes
- Encourage uptake of ELN recommendations for the management of CML, and measure clinical benefit of their implementation
- Inform effective treatment decisions via enhanced tracking of disease progression and treatment resistance

Initiatives to be undertaken as part of the Alliance include:

- Implementation and enlargement of the existing ELN CML patient registry to collect baseline, treatment and outcome data of representative samples of CML patients in European countries. This enhanced bank of real world data will help measure clinical effects of the implementation of ELN recommendations on CML management
- Expansion of the availability of molecular monitoring for CML patients. This program aims to reshape existing European infrastructure, to use standardized procedures for the molecular monitoring of CML and will facilitate the investigation of response and acquired resistance to existing treatments, helping to inform therapeutic choices for these patients
- Rapid expansion of availability of monitoring of the selective tyrosine kinase inhibitor imatinib, to develop a Europe-wide pharmacological monitoring service to optimise therapy with the drug. Data collected during the two year program will be analysed to investigate the most effective level of blood concentration of imatinib
- Educational initiatives, including a web portal, data publications and presence at scientific congresses, to inform and educate healthcare professionals involved in the management of CML on the activities of the Alliance and to share learnings and best practice

About the European Leukaemia Network

The ELN is a Network of Excellence which is founded by the European Commission representing 133 academic institutions and unites over 1,000 researchers in 24 countries with the aim of research collaboration to make leukemia a curable disease. The ELN's work in CML is intended to improve understanding about, and treatment of, the disease.

ELN members from France, Germany, Italy, Spain, Sweden, Switzerland and the United Kingdom have worked with experts from Australia and the United States of America to provide the medical community with an updated and critical review of the treatment of CML and with recommendations for the appropriate use of new treatments.¹

To encourage incorporation of such recommendations into clinical practice, the ELN is undertaking a number of national and international studies running in Spain, France, Italy, Germany, Scandinavian and other European countries and has established a European Registry to register, treat and monitor as many patients with CML as possible in controlled, prospective, investigational or observational studies.

About chronic myeloid leukemia (CML)

CML is one of the four most common types of leukemia. It is the result of an abnormality in the stem cells of the bone marrow. The abnormality can be found in a faulty gene, which is the blueprint for a protein involved in controlling the production of white blood cells. The resulting abnormal protein causes a massive increase in the number of white blood cells. CML usually develops very slowly, which is why it is called 'chronic' myeloid leukemia. Chronic myeloid leukemia can occur at any age, but it more commonly affects middle-aged and older people. It is rare in children.

CML has historically been treated with chemotherapy, interferon and bone marrow transplantation; however, the introduction of targeted therapies - medications which block the growth of cancer cells by interfering with specific targeted molecules (the abnormal protein) needed for carcinogenesis and tumor growth, rather than by simply interfering with rapidly dividing cell - have radically changed the management of CML. Targeted cancer therapies may be more effective than current treatments and less harmful to normal cells.

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References

1. Baccarani M et al, Blood 2006;108:1809-1820