



Contact: Rebecca Hibble / Vicky O'Connor

Tel: +44 (0)7813 096 161 / + 44 (0)7894 386 428

Email: rebecca.hibble@cohnwolfe.com / vicky.oconnor@cohnwolfe.com

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European Treatment and Outcome Study for Chronic Myeloid Leukemia Secures Funding for a Further Two Years

Three-Year Results Show Patient Care Significantly Advanced

Vienna, October 21, 2010 – The assessment, treatment and monitoring of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) through the European Treatment and Outcome Study (EUTOS) for CML has now been extended beyond its original scope for a further two years, it was announced today.

EUTOS was initiated in 2007 in response to the vast differences across Europe in the monitoring and treatment of Ph+ CML, which affects one to two people per 100,000 per year.¹ The program was developed to enhance understanding of the nature and management of CML, improve standardized evaluation and monitoring of the condition, and optimize diagnosis and treatment across Europe.

“Within a short space of time, we have seen significant developments in the management and treatment of CML as a result of the European Treatment and Outcome Study,” said Prof. Michele Baccharani, Università di Bologna, Italy, a lead investigator.

Based on the success of the program, Novartis has committed an additional six million Euros to facilitate the evolution of EUTOS. The program will be revised and enhanced to reflect the most recent advances in the treatment and management of Ph+ CML and will have several strategic areas of focus.

The extended program is based on the shared vision of Novartis and the scientific community to strive towards a path to cure for Ph+ CML. “By continuing our work across Europe, we now have greater opportunities to maximize the way patients are treated and to ultimately improve their outcomes,” said Dr. Guido Guidi, Head, Region Europe, Novartis Oncology.

The enhanced EUTOS program will feature a ‘*Path to Cure*’ Working Group for Ph+ CML that will bring together European experts on the treatment of CML and Novartis scientists to work in partnership on strategies and implement projects focused on improving the treatment of Ph+ CML even further. This Working Group is the first step

within a broad strategy being pursued by Novartis that is dedicated to bringing an overall cure to patients so that they may ultimately be able to discontinue their therapy.

A prospective, population-based patient registry, which will target more than 2,000 patients for enrollment, will assess the treatment of newly diagnosed patients in all countries across Europe, the first of its kind in CML.

“The EUTOS for CML program has contributed significantly to our understanding of CML and the ability to effectively manage the condition. With the continuation of the program we will have access to the largest CML population ever studied,” said Prof. Rüdiger Hehlmann, chair of the European LeukemiaNet. “From the data contained within the existing registry, the EUTOS working group has been developing a new prognostic score that aims to make it easier to calculate the risk of disease progression than with existing methods.”

In the new EUTOS project, greater emphasis will be placed on the importance of molecular monitoring in Ph+ CML to ensure the disease is followed with the most sensitive methods currently available. Fundamental to this is the goal of enabling all laboratories within the EUTOS project to reach a higher level of precision in disease detection. Increased sensitivity of the test is a tool in finding a path to a cure in CML.

Three Year Results of EUTOS

In the past three years, the four key projects of EUTOS have provided important data for disease and therapeutic monitoring:

- **Patient registry:** Target enrollment of 4,000 patients has been achieved; this provides a clear picture of Ph+ CML patient treatment and outcomes across Europe to support understanding and management of the disease.
- **Molecular monitoring:** 51 reference molecular monitoring laboratories across 28 countries have been successfully standardized, ensuring that reliable, comparable results are secured to monitor disease status and inform treatment decisions.
- **Pharmacological monitoring:** Approximately 10,000 imatinib blood level tests have been analyzed and 47 laboratories have been validated for measuring blood levels.
- **Spread of Excellence:** More than 2,000 physicians and hematologists have participated in educational programs in the past three years.

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Notes to Editors

2007 - 2010 EUTOS Projects

Patient registry

The patient registry improves understanding of Ph+ CML, providing unique documentation of 'real world' treatment and outcomes, tracking baseline, treatment and outcomes data from patients across Europe.

Molecular monitoring

Molecular response to treatment, as measured by a steady decline in Bcr-Abl gene transcript levels, indicates an ideal response to therapy. Molecular monitoring has become widely available through the use of the real-time quantitative polymerase chain reaction (RQ-PCR) methodology. This methodology is the most sensitive one available and has been found to correlate with both cytogenetic response – measurement of the number of Philadelphia chromosome-positive cells, which are responsible for CML, in the bloodstream – and progression-free survival.

Pharmacological monitoring

Blood level testing is a simple and effective way to support the management of patients who may not be adhering to their treatment, those who are not responding as expected, and those who may be experiencing drug-drug interactions or unusually severe side effects at the prescribed dosage.

The testing is conducted in a central facility in Bordeaux or in one of the 47 standardized laboratories now established in countries across Europe.

Spread of Excellence program

A program encompassing educational events and materials to inform clinicians about the optimal management of Ph+ CML, the Spread of Excellence initiative has produced a dedicated website, scientific publications and physician resources including newsletters, slide kits and resource packs. More than 2,000 physicians and next-generation hematologists have attended pan-European educational meetings and training courses.

About the European LeukemiaNet (ELN)

The ELN was established by the European Community in 2004 to strengthen scientific and technological excellence in research and treatment of Ph+ CML and other leukemias by integrating the leading national leukemia networks and their interdisciplinary partner groups in Europe.

The ELN comprises 175 participating centers in 33 countries, and has more than 1,000 researchers and associates cooperating to share knowledge and expertise in the treatment of CML.

About chronic myeloid leukemia

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 the Philadelphia chromosome, which gives rise to 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, but is ultimately fatal. CML can occur at any age, but it more commonly affects middle-aged and older people. It is rare in children.

EUTOS for CML is a collaborative initiative between the European LeukemiaNet and Novartis Oncology, funded by Novartis

For further information, please visit the EUTOS for CML website at www.eutos.org

Reference

¹ Central European Leukemia Study Group. About CML. Accessed 27 September 2010. <http://www.cml-info.com/de/healthcare-professionals/about-cml.html>