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**New Data from European Treatment and Outcome Study for CML
Demonstrate Need for Improved Management and Dose Optimization
Across Europe**

Cannes, October 17, 2008 – One-year data from the European Treatment and Outcome Study (EUTOS) for Chronic Myeloid Leukemia (CML), presented here today, provide a clear rationale for the initiative's program of close disease management and therapeutic monitoring. Improved access to blood level testing and disease monitoring through the EUTOS for CML program can help physicians optimize treatment in patients with CML, a type of cancer that affects 1 to 2 people per 100,000,¹ with as many as 60,000 people with CML in Europe.

EUTOS for CML, a collaboration between the European LeukemiaNet (ELN) and Novartis, is a unique program to improve treatment and outcomes for patients. EUTOS for CML aims to achieve these goals by obtaining a pan-European "real-world" picture of incidence, treatment and outcomes of CML patients through an expanded patient registry, and by improving access to state-of-the art monitoring techniques to assess disease progression and optimize treatment.

"The EUTOS for CML one year data demonstrate that access to this monitoring program will allow patients to achieve improved response to treatment and have a better chance of survival," said Rüdiger Hehlmann, of the University of Heidelberg, Germany and ELN chair. "The unique collaboration between the ELN and Novartis is already improving outcomes for patients by helping to standardize management of CML and providing access to the latest monitoring techniques."

Patient registry

The EUTOS for CML registry is tracking baseline, treatment and outcomes data from patients across Europe. To date the registry has recruited 2,500 patients across 11 countries to provide clear documentation of treatment and outcomes in CML.

"We are extremely pleased with the progress of the EUTOS for CML program over the past year," said François Guilhot, of the University of Poitiers, France. "Our expanded registry is building a unique record of the incidence and management of CML all over Europe. An additional 1,700 patients will be recruited into a prospective study group to track the implementation of ELN recommendations and their clinical impact."

Molecular monitoring

In addition, EUTOS for CML has standardized molecular monitoring techniques, used to track disease status, in 27 of a target 50 laboratories in Europe, with complete standardization on track for 2009. Patients in 27 countries can now access state-of-the-art, standardized techniques to monitor their disease.

Molecular response to treatment, as measured by assessment of Bcr-Abl gene transcript levels, has become widely available through the use of the real-time quantitative polymerase chain reaction (RQ-PCR) methodology. This methodology is the most sensitive to determine cytogenetic response – the elimination of Ph-positive cells responsible for CML – which is also correlated with progression-free survival.^{2,3}

“The use of different testing methods can produce variations in measured responses among laboratories and, until now, it has been essential for patients to be tested in the same laboratory over time to ensure comparable results,” said Michele Baccarani, of the University of Bologna, Italy. “Reliable and timely molecular monitoring will mean fewer tests for patients and also means that their progress can be monitored no matter where they are in Europe. It also allows doctors to compare results.”

Pharmacological monitoring

A further key element of the EUTOS for CML program is the standardization and expansion of imatinib blood level testing via the pharmacological monitoring program which aims to optimize treatment response where needed. The majority of patients treated with imatinib as first-line therapy achieve high overall rates of complete hematologic and cytogenetic response,⁴ where the patient’s blood cell counts return to normal. Monitoring of imatinib blood levels is important for those patients who may not be adhering to their treatment, those who are not responding as expected or those who may be experiencing drug-drug interactions or unusually severe side effects at the prescribed dosage.

As of today more than 1,100 blood level samples from these types of patients have been collected and analyzed by a central facility in Bordeaux. Significantly, preliminary results indicate that around 60% of those samples had imatinib levels lower than those associated with the best responses to imatinib treatment⁵, indicating that there is a valuable correlation between testing and a patient’s response to imatinib treatment. The testing is provided as a free service to patients and healthcare providers as part of the EUTOS for CML initiative.

A growing database of blood level measurements from EUTOS for CML may provide evidence to support the incorporation of imatinib blood level testing as a part of standard practice in the management of CML. Regular blood level testing is a simple and effective way to evaluate patient treatment and may help improve patient outcomes for patients.

“Novartis is delighted with the progress made by the EUTOS for CML program after only one year. It is already having a significant impact on improving the treatment of CML,” said Guido Guidi, Novartis Oncology Head, Region Europe. “Novartis is committed to this unique partnership with the European LeukemiaNet, which is the first collaboration of its kind. We very much look forward to the availability of the final data analysis from the program.”

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

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

To view the media briefing on 17th October via webcast, please visit <http://www.webcast4007.com/eutos-for-cml/>

Notes to Editors

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 CML and other leukemias by integrating the leading national leukemia networks and their interdisciplinary partner groups in Europe.

The ELN comprises 147 participating centers in 28 countries, and has more than 1000 researchers and associates cooperating to share knowledge and expertise in the treatment of CML.

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.⁴

To encourage incorporation of such recommendations into clinical practice, the ELN is undertaking a number of national and international studies in Spain, France, Italy, Germany, Scandinavia 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 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, the so-called Philadelphia chromosome 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. In 2002 the introduction of imatinib, the first molecularly targeted therapy for Philadelphia chromosome-positive CML, radically changed the management of this disease. Targeted therapies block the growth of cancer cells by interfering with specific targeted molecules needed for carcinogenesis and tumor growth, rather than by simply interfering with rapidly dividing cells. Targeted cancer therapies may be more effective than older treatments and less harmful to normal cells.

As a result survival rates for CML have substantially improved.

About Novartis

Novartis AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group's continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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³ Kantarjian HM, O'Brien S, Cortes JE, et al. Complete Cytogenetic and Molecular Responses to Interferon- α -Based Therapy for Chronic Myelogenous Leukemia Are Associated with Excellent Long-Term Prognosis. *Cancer*. 2003;97:1033-1041

⁴ O'Brien SG, Guilhot F, Larson RA et. al. Imatinib compared with interferon and low-dose cytarabine for newly diagnosed chronic-phase chronic myeloid leukemia. *N Engl J Med*. 2003; 348:994 – 1004

⁵ Mahon XF. Bordeaux 2008, data on file.