



## **Cytheris Announces New Phase I Study of Interleukin-7 As Immunotherapy In Treatment of Bone Marrow or Peripheral Blood Stem Cell Transplant Patients**

**Clinical trial is designed to investigate use of IL-7 in treatment of immunodeficient transplant recipients who are vulnerable to a variety of bacterial, viral, and fungal infections**

Paris – April 23, 2008 – Cytheris SA, a clinical stage biopharmaceutical company focused on research and development of new therapies for immune modulation, today announced the initiation of a Phase I clinical trial of its lead investigational drug candidate, Interleukin-7 (IL-7), also known as CYT107. This new trial will study the use of IL-7/CYT107 in the treatment of post-transplant patients with T-cell depleted bone marrow or peripheral blood stem cell transplants. The initial study site will be at Memorial Sloan-Kettering Cancer Center (MSKCC) in New York City, where Marcel R.M. van den Brink, M.D., Ph.D., Head, Division of Hematologic Oncology, and Miguel-Angel Perales, M.D., Assistant Attending Physician in the Bone Marrow Transplant Service, will serve as Principal Investigator and co-Principal Investigator, respectively. Additional study sites are expected to open in the United States during the coming months.

Recombinant human Interleukin-7 (r-hIL-7) is a critical growth factor for immune T-cell recovery and enhancement. Clinical trials conducted on more than 75 patients in Europe, the United States and Canada have suggested the potential of r-hIL-7 to expand and protect CD4+ and CD8+ T-cells. Cytheris is currently conducting multiple international clinical studies of IL-7 in HIV, HCV and cancer.

“We share a commitment with MSKCC to addressing the unmet medical need that exists for cancer patients who are frequently in a profoundly immunodeficient state following the bone marrow transplant procedure, leaving them susceptible to a variety of bacterial, viral, and fungal infections,” said Michel Morre, DVM, President and CEO of Cytheris. “MSKCC has for many years been in the forefront of stem cell transplantation therapy in the U.S. and we are therefore especially pleased that Drs van den Brink and Perales have agreed to participate in this study which we hope will ultimately lead to the development of therapies to prevent post-transplant infections which so often contribute to the failure of hematopoietic stem cell allografts .”

### **About the Study**

Delayed and deficient reconstitution of T-cell populations and their functions constitute a major obstacle to the success of a hematopoietic stem cell allograft. Experimental

studies demonstrate that IL-7 can promote recovery of thymopoiesis, peripheral lymphoid populations and their functions in murine recipients of allogeneic hematopoietic stem cell transplantation (HSCT) without augmenting Graft versus Host Disease (GVHD). Patients admitted to the study must have histologically confirmed non-lymphoid hematological malignancy such as acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), myelodysplastic syndrome (MDS), a history of an opportunistic infection (including but not limited to CMV viremia requiring anti-viral therapy), PCP pneumonia, mycobacterial infection, herpes zoster, or viral respiratory infection (influenza, RSV, para-influenza), and have a CD4<sup>+</sup> T-cell count < 100 at 2 months post-transplant.

The primary objective of the investigation is to determine the safety and a recommended dose of CYT107 in recipients of an HLA-matched related or unrelated ex vivo T-cell-depleted bone marrow or peripheral blood stem cell transplant after initial engraftment and hematopoietic reconstitution. If toxicities are encountered, the study will also seek to establish the maximum tolerated dose (MTD) and dose limiting toxicities (DLT).

**About Cytheris – [www.cytheris.com](http://www.cytheris.com)**

Cytheris SA is a privately held clinical-stage biopharmaceutical company focused on research and development of new therapies for immune modulation. These drugs aim at reconstituting and enhancing the immune system of patients suffering from cancer, chronic viral or bacterial infections such as HIV and HCV, or lympho-depleting treatments such as chemotherapy, radiotherapy, bone marrow transplantation (BMT) and hematopoietic cell transplantation (HCT).

The company's lead compound, recombinant human Interleukin-7 (r-hIL-7), is a critical growth factor for immune T-cell recovery and enhancement. Clinical trials conducted on more than 75 patients in Europe and North America have suggested the potential of r-hIL-7 to expand and protect CD4<sup>+</sup> and CD8<sup>+</sup> T-cells. The Company is currently conducting multiple clinical studies of IL-7 in HIV, HCV and cancer.

The company operates from its headquarters and laboratories in Issy-les-Moulineaux, a suburb of Paris, and its U.S. subsidiary in Rockville, Maryland.

**For more information, please contact:**

**French/International media inquiries -- Andrew Lloyd & Associates:**

Andrew Lloyd ([allo@ala.com](mailto:allo@ala.com)), Gilles Petitot ([gilles@ala.com](mailto:gilles@ala.com))

Tel: +33 1 5654 0700

# # #