Cytheris launches a new Phase I clinical trial in the US for its recombinant Interleukin-7

Study in the Memorial Sloan Kettering Cancer Center targets immunodeficiency in patients with Hematopoietic Cell Transplants (bone marrow, blood stem cells)

Paris, September 19, 2005 — Cytheris, a biopharmaceutical company focused on immuno-modulation, announced today the start of a fifth Phase I clinical study in the Memorial Sloan Kettering Cancer Center (NY). The trial relates to the administration of its lead compound, a recombinant Interleukin-7 (rIL-7), in patients with myeloid malignancies (Acute Myeloid Leukemia, Chronic Myeloid Leukemia, Myelodysplastic Syndrome) who underwent a T cell depleted allogenic Hematopoietic Cell Transplant (HCT). rIL-7 is a pivotal growth factor with unique properties to reconstitute the immune system and enhance global and specific immune responses.

Hematopoietic Cell Transplant (HCT) from an allogenic related or unrelated donor has the potential to cure malignant leukemia or other malignant hematological diseases, which are usually fatal if treated only with conventional chemo-radiotherapies. *In vitro* T cell depletion HCT can considerably reduce the Graft-vs.-Host-Disease (GvHD) risk associated with traditional HCT but in some cases can also increase the risk of relapse. Moreover, it generally slows down the post-graft immune reconstitution, thus exposing patients to life threatening infections.

Cytheris' rIL-7 has shown significant therapeutic potential in repeated successful preclinical studies, and this has led Cytheris to launch a Phase I/II study to further evaluate its potential on the enhancement of the immune recovery and the decrease of the post-transplant infectious risk in this group of patients.

This Phase I/II trial will take place in the US at the Memorial Sloan Kettering Cancer Center (MSKCC), with two leading investigators in this field: Dr. Richard O'Reilly and Dr. Marcel Van Den Brink. This trial will aim at confirming rIL-7 safety and demonstrating preliminary efficacy on surrogate markers such as the speed of lymphocyte recovery (CD4 cell) and its persistence after treatment completion. This set of information will be critical in order to design the subsequent phase II study.

"We are very excited to start this trial in this setting, where rIL-7 should demonstrate its pivotal role for the immune reconstitution of those patients exposed to life threatening infections," said Michel Morre, CEO of Cytheris. "This is now our second phase I/II study addressing this problem in lymphopenic patients. Our objective is to confirm what we already observed so far in cancer patients and numerous preclinical studies and pave the way for Phase II/III

studies that should demonstrate, in the relatively short-term, the clinical benefit resulting from rIL-7 treatment in those immunodeficient patients."

This study is expected to be the final one in an ambitious program of five Phase I/II studies across both sides of the Atlantic in HCT, HIV and Cancer. Cytheris has already completed a Phase I trial and the other Phase I/II studies are on-going. As of today, more than 30 patients have been treated and results confirm the good safety profile and high efficacy level of rIL-7.

About Cytheris

Cytheris, Paris, is a product-oriented biopharmaceutical company focused on the research and development of new and critical agents for immune modulation. These drugs aim at reconstituting, enhancing or modulating the immune system activity of patients suffering from life-threatening diseases. The company's lead compound is a recombinant Interleukin-7 (rIL-7). The second family of products is based on NKT ligands in-licensed from New-York University, the Aaron Diamond AIDS Research Center and the City University of New-York. Cytheris has a strong network of collaborations with internationally renowned academic and clinical teams as well as industrial partners. The company was founded in 1999 and today employs around 20 experienced people in Europe and in the USA. The company, based in Vanves, Paris, has a subsidiary in Rockville (MD-USA), and is currently raising a B Round to fund early Phase II clinical trials. Current investors include AXA Private Equity, Bioam, Crédit Agricole Private Equity, T2C2/Bio 2000 (Canada) and CDP Capital-Technologies (Canada). Website: www.cytheris.com