

**PRESS RELEASE 11/7/05**

## **Cytheris launches two new Phase I clinical trials for its recombinant Interleukin-7**

**Studies in US and France target immunodeficiency in HIV infected patients**

Paris, July 11, 2005—Cytheris, a biopharmaceutical company focused on immuno-modulation, announced today the start of two new Phase I clinical studies. The trials relate to the administration of its lead compound, a recombinant Interleukin-7 (rIL-7), in HIV-infected patients. rIL-7 is a pivotal growth factor with unique properties to reconstitute the immune system and enhance global and specific immune response.

Cytheris' decision to initiate two Phase I clinical studies in HIV patients came as a result of positive data from a recently completed Phase I clinical study in cancer. These showed an excellent tolerance together with a quick and significant expansion of patients' T lymphocytes, including CD4 T Cells, which protect from infection but are invaded and destroyed by HIV. Another reason for Cytheris' decision to go ahead was preclinical data demonstrating the safety of rIL-7 administration in SIV infected monkeys, a primate model of HIV infection.

The first multicenter study has been launched in the US in collaboration with the NIH/ACTG (National Institutes of Health AIDS Clinical Trials Group), and the first patients have been already enrolled. The second study will take place in France in five different clinical centers in the Paris area. The study has been approved and is ready to start in September.

The objective of these two studies is to establish the safety of the product in HIV-infected patients, and provide relevant surrogate markers to document the rIL-7-induced immune reconstitution. They will also provide valuable information for the design of Phase II clinical trials and the translation of this activity into clinical benefit in HIV patients.

“These trials will strongly support our clinical strategy in HIV,” said Michel Morre, CEO of Cytheris. “We are optimistic that rIL-7 will confirm the CD4 T cell expansion that we already observed in cancer patients and will bring additional proof-of-concept that the product is really the key critical factor to restoring the immune system in many immunodeficiency settings.”

Those two trials are part of an ambitious Phase I/II program made up of five studies in various indications. A first Phase I trial has been completed and three others are on-going. As of today, more than 25 patients have been treated.

### **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/Biogestion, Crédit Agricole Private Equity, T2C2/Bio 2000 (Canada) and CDP Capital-Technologies (Canada). Website: [www.cytheris.com](http://www.cytheris.com)  
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