



## **Cytheris to start two phase I/IIa clinical trials of CYT107, its new recombinant Interleukin-7, in Hepatitis C and oncology**

Paris, May 31, 2007—Cytheris, a product-oriented biopharmaceutical company focused on the research and development of new and critical agents for immune modulation, today announced it will start two phase I/IIa clinical trials of its CYT107 recombinant interleukin in Hepatitis C and oncology. These follow the successful completion of four phase I studies. The company expects these new trials to confirm IL-7's potential in building immune system response.

The Hepatitis C trial (CYT107-05) will concern HCV infected patients that are non-responders to the reference treatment (12 weeks of PEG-Interferon + Ribavirin). This multicentric dose escalation study (France, Switzerland) will include 12-18 patients. They will receive CYT107 (rh-IL-7) injected weekly over 4 weeks in addition to their reference treatment. More than one third of the patients do not respond to the reference treatment because they are unable to mount an efficient immune response against the virus. Cytheris expects the addition of CYT107 treatment to restore appropriate T cell function and help these patients better cope with the virus.

The oncology trial (CYT107-04) targets patients with metastatic melanoma or advanced renal cell carcinoma. It will include 18 to 30 patients, both lymphopenic and non-lymphopenic in a dose escalation mode. It will be conducted at NCI (Bethesda, MD USA) in collaboration with Prof. Steve Rosenberg. Most recent clinical data demonstrate how critical the immunological status of cancer patients is for their clinical outcome. CYT107 is expected to boost patients' immune responses against their tumor. This will be important in the treatment of post-chemotherapy residual diseases and/or to support efficacy of various cancer vaccine approaches.

"These two new trials should help confirm the strong potential of IL-7 in reconstituting the immune system and enhancing the specific immune response against various fatal infectious or malignant diseases," said Michel Morre, CEO of Cytheris. "These two studies form part of Cytheris's ambitious phase I/II program. Four phase one studies of recombinant human IL-7 have already been completed in oncology and HIV in both France and the US. As of today, more than 60 patients have been treated, with encouraging results which we have presented in many international meetings such as AACR and ASCO US 2006, ASH 2006 and CROI 2007."

Although the primary objectives of these trials consist in establishing the safety and pharmacokinetic profiles of CYT107, biologically active doses will be sought based on the measures of a full set of immunological surrogate markers together with the control of the viral load in the HCV study and tumor growth and extension in the oncology study.

Main results for both studies should be available in the second quarter of 2008 opening the door to larger phase II studies.

### **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 and enhancing the immune system of patients suffering from cancer, chronic viral or bacterial infections (such as HIV and HCV) or lympho-depleting treatments (e.g. post-chemo,-BMT and -HCT).

The company's lead compound, recombinant Interleukin-7 (rIL-7) is a critical growth factor for immune T Cell recovery and enhancement. Clinical trials conducted on more than 60 patients in France and USA have already demonstrated the impressive ability of rIL-7 to expand and protect CD4+ and CD8+ T cells.

A second family of products is based on highly potent NKT/dendritic cell ligands, in-licensed from several New York universities. The product family strengthens innate and adaptive immunity connections and will provide new immuno-therapeutic adjuvants for cancer and chronic infectious diseases.

The company, founded in 1999, operates from Issy les Moulineaux, Paris and its US subsidiary in Rockville (MD). It has a network of strong and active collaborations with world-leading academic and clinical teams. Today Cytheris employs 22 experienced people in Europe and USA. Its investors include AXA Private Equity, Bioam Gestion, Credit Agricole Private Equity and CDC Innovation (Paris), T2C2 Bio2000 and CDPQ (Montreal), Forbion Capital Partners (Amsterdam). Website: [www.cytheris.com](http://www.cytheris.com)

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