



Cytheris Announces Notice of Allowance for U.S. Patent Covering the Pharmaceutical Composition of its Recombinant Human Interleukin-7 (CYT107)

Paris (France) – July 8, 2009 – Cytheris SA, a clinical stage biopharmaceutical company focused on research and development of new therapies for immune modulation, today announced that it has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for its patent application "IL-7 Drug Substance, Composition, Preparation and Uses", US Patent Application Number 10/522,883. The Notice of Allowance is the USPTO's official communication that the Company's application has successfully completed examination and that a patent will be issued.

"We are pleased to announce receipt of this Notice of Allowance by the USPTO," said Michel Morre, DVM, President and CEO of Cytheris. "Once issued, this patent along with other previously issued patents will provide broad protection for Cytheris' recombinant human interleukin-7 (CYT107), a critical immune-modulator for immune T-cell recovery and enhancement, and extend this protection in the U.S. to 2022."

This patent covers the efficient IL-7 pharmaceutical composition which should contain not only the specific IL-7 conformer as the major constituent, but should also be essentially devoid of other conformers or IL-7 molecular variants, previously considered as active products. The patent incorporates the combination of all this information as necessary to design and produce an ideal IL-7 pharmaceutical composition. The patent stems from the unexpected discovery that the long term activity of recombinant IL-7 is mostly expressed by a specific conformer and that other conformers, potential product-related substances, product-related impurities, and process-related impurities, which would normally be included in the specification of the drug substance and/or drug product, although bioactive, should be strictly minimized because they are able to trigger an immune reaction against the desired IL-7 molecule.

Considerable evidence from basic immunology, preclinical models and, more recently, from clinical studies, confirms the unique role of IL-7 in the functioning of the immune system and especially in providing the right cells in sufficient numbers to support and improve specific immune responses against infectious agents and malignant cells. In that light, as with EPO for red blood cells and G-CSF for neutrophils, IL-7 plays a pivotal role in supporting T cell expansion and function.

IL-7 was originally discovered by Immunex Corporation (now part of Amgen) and through a process of intellectual property acquisition resulting from several mergers, the compound eventually ended up at what is today Sanofi-Aventis, from whom Cytheris holds the exclusive worldwide license. Cytheris also holds the rights to an additional IL-7 patent family acquired under an exclusive worldwide license from the Washington Research Foundation of the University of Washington, Seattle.

As the exclusive licensee, Cytheris holds all original patents protecting IL-7 and various uses including the use for T cell expansion and for enhancing humoral and cellular immunity.

In addition Cytheris has filed patent applications protecting the purified protein as a drug substance for therapeutic use with the correct disulfide bridging, the appropriate glycosylation profile and polypeptidic purity. These patents also protect various hyperglycosylated analogs and various fusion proteins.

About Interleukin-7 (CYT107)

Recombinant human interleukin-7 (CYT107) is a critical immune-modulator for immune T-cell recovery and enhancement. As a growth factor and cytokine physiologically produced by marrow or thymic stromal cells and other epithelia, IL-7 has a critical and, at some steps, a non-redundant stimulating effect on T lymphocyte development, notably on thymopoiesis and, downstream from the thymus, on homeostatic expansion of peripheral T-cells.

A first-generation form of rhIL-7 was shown in pre-clinical and Phase I studies in oncology and HIV-infected patients to be well tolerated in repeated dose trials, with long-lasting increases in both CD4 and CD8 T cells. CYT107 is a second-generation rhIL-7 product made by Cytheris via a recombinant mammalian cell culture system.

Clinical trials conducted on more than 110 patients in Europe, North America and Taiwan have demonstrated the potential of IL-7 to expand and protect CD4+ and CD8+ T-cells. Currently, Cytheris is conducting multiple international investigations of IL-7 in HCV, HIV and cancer, with trials for other indications planned to initiate in 2H09.

About Cytheris' Interleukin-7 Clinical Development

Ongoing clinical development includes six interpatient dose escalation studies, with starting doses varying from 3 µg/kg/week to 60 µg/kg/week, to evaluate the safety and biological activity of CYT107 in various indications. These studies include:

- **CLI-107-04:** a monocentric Phase I interpatient non-controlled dose escalation study in oncology (metastatic melanoma or renal cell carcinoma), conducted at the US National Cancer Institute, Bethesda, Maryland.
- **CLI-107-06 (the INSPIRE study):** a Phase I/IIa interpatient dose escalation randomized placebo-controlled, single-blind, multicenter study in HIV-infected patients, conducted in the United States, Canada, Italy and France.

- **CLI-107-05 (ECLIPSE-1):** a Phase I multicenter, non-controlled interpatient dose escalation study in treatment-naive, non-responder (no Early Viral Response (EVR) at week 12) HCV infected patients conducted in France, Italy and Switzerland assessing CYT107 in combination with a peg-interferon (peg-IFN) and Ribavirin (RBV) bi-therapy.
- **CLI-107-07 (ECLIPSE-2):** a Phase I/IIa non-controlled dose escalation study in HCV-infected patients, conducted in France and Italy, evaluating CYT107 in combination with peg-IFN and RBV bi-therapy in patients with genotype 1 and 4 previously non-responsive to standard treatment.
- **CLI-107-09 (ECLIPSE-3):** a Phase I/IIa non-controlled dose escalation study in chronically infected HCV patients, conducted at multiple sites in Taiwan, evaluating CYT107 in combination with peg-IFN and RBV bi-therapy in patients with genotype 1 previously non-responsive to standard treatment.
- **CLI-107-08:** a monocentric Phase I non-controlled interpatient dose escalation study in recipients of HLA-matched ex-vivo T-cell-depleted bone marrow or peripheral blood stem cell transplant to restore CD4+ and CD8+ counts following T-cell depletion, conducted at the Memorial Sloan-Kettering Cancer Center in New York City.

About Cytheris – 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 HCV, HBV and HIV, or lympho-depleting treatments such as chemotherapy, radiotherapy, bone marrow transplantation (BMT) and hematopoietic cell transplantation (HCT). The company operates from its headquarters and laboratories in Issy-les-Moulineaux, a suburb of Paris, and its U.S. subsidiary in Rockville, Maryland.

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