



## **ATIR classified as “cell based” medicinal product by the EMEA**

### **A classification for innovative new treatments**

**Amsterdam, 14 December, 2007** - Kiadis Pharma announced today that its lead product ATIR has received approval for regulatory classification as a “cell based” medicinal product by the Innovation Task Force (ITF), a division of the European Medicines Agency (EMA). Based upon this regulatory classification ATIR is eligible for EMA procedures. As a next step Kiadis Pharma will file for orphan drug designation with the EMA to obtain additional product protection upon marketing approval. In November this year ATIR has been granted orphan drug designation by the US Food and Drug Administration (FDA).

ATIR is under development to prevent acute Graft versus Host Disease (GvHD) allowing the use of a mismatched donor for bone marrow transplantations. It is a personalized cell-based treatment prepared according to a proprietary protocol using both a novel small molecule substance and a proprietary medical device. With the official classification of ATIR as a cell based medicinal product by the EMA, it is now categorized as an Advanced Therapy, and considered to be a highly innovative treatment. The benefits are a centralized marketing authorization procedure, which harmonizes and facilitates access to the European market. In addition, it provides access to an expert Committee for Advanced Therapies within the EMA, to address scientific, legal and regulatory issues during product development.

*“We are very pleased having received a cell based medicinal product classification for ATIR. The regulatory guidelines that will rule ATIR are therefore clear and we have subsequently started with the application of the orphan drug designation with the EMA which will be filed before the end of this year”,* said Manja Bouman, CEO Kiadis Pharma.

#### **About ATIR**

ATIR is designed to prevent life-threatening acute graft versus host disease (GvHD) by eliminating the immune cells from the donor graft that otherwise attack the patient’s body. Useful donor immune cells that can fight infections and remaining tumor cells are, however, spared, allowing rapid and safe donor immune reconstitution post transplantation. Acute GvHD is a major complication of allogeneic bone marrow transplantations. By preventing the occurrence of acute GvHD, ATIR enables the use of a mismatched donor and consequently addresses a significant limitation in bone marrow transplantation, the timely availability of a donor. Moreover, it could improve the general outcome of bone marrow transplants.

#### **About Kiadis Pharma**

Kiadis Pharma is an oncology company focused specifically on complications and limitations of bone marrow transplantations in blood cancer patients. The company has three products in clinical development that offer novel treatment options for terminally ill blood cancer patients and address high-unmet medical needs. Kiadis Pharma is headquartered in Amsterdam, the Netherlands with facilities in Groningen, The Netherlands and Montreal, Canada. For more information about Kiadis Pharma, please visit [www.kiadis.com](http://www.kiadis.com).

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