



FDA grants Kiadis Pharma lead product ATIR orphan drug designation

Amsterdam, November 7, 2007 – Kiadis Pharma announced today that its lead product ATIR has been granted orphan drug designation by the US Food and Drug Administration (FDA) as a therapy for immune reconstitution and prevention of Graft versus Host Disease (GvHD) following allogeneic bone marrow transplantation. ATIR is currently in phase I/II clinical studies and anticipated to enter clinical phase III studies in 2008.

"This is an important strategic milestone in the development of ATIR as a novel approach which may enable a safe and potentially life-saving mismatched bone marrow transplantation as a treatment option for end-stage blood cancer patients" said Dr. Manja Bouman, Chief Executive Officer of Kiadis Pharma.

The FDA's orphan drug designation is reserved for new therapies being developed to treat diseases or conditions that affect fewer than 200,000 people in the United States. The orphan drug designation provides for an accelerated review process, tax benefits, exemption from user fees and a seven-year period of market exclusivity in the US after product approval.

ATIR is under development to prevent life-threatening GvHD, a major complication of allogeneic bone marrow transplantations. GvHD is a condition caused by the donor immune cells attacking the patient's tissues and organs. Allogeneic bone marrow transplantations today require that the patient and donor immune systems (HLA type) are highly similar in order to reduce the risk of GvHD and therefore rely on matching donors. By preventing the occurrence of 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.

Every year between 50,000 and 60,000 patients die of blood cancers in the United States alone. For these end-stage and high-risk blood cancer patients bone marrow transplantation is the only treatment option. In addition, a number of other hematological diseases can be cured by bone marrow transplantations. However, annually only about 2,500 patients in the United States receive a transplantation with bone marrow from an unrelated matched donor despite the approximately 60,000 worldwide initiated searches for a matching donor in the donor registries.

About ATIR

ATIR is designed to prevent GvHD by selectively eliminating the immune cells that otherwise attack the patient's body. ATIR is also designed to spare useful immune cells that can fight infections and remaining tumor cells that would allow rapid and safe immune reconstitution post transplantation. Prevention of GvHD using ATIR could therefore make the safe use of mismatched bone marrow donors possible. Moreover, it could improve the outcome of matched bone marrow transplants.

About Kiadis Pharma

Kiadis Pharma is an oncology focused pharmaceutical development company with four products in different phases of clinical development. The company develops products that offer novel treatment options for terminally ill cancer patients and address significant unmet medical needs. The key focus indication for Kiadis Pharma is limitations and complications of bone marrow transplantation procedures performed in blood cancer patients. 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.

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