



## Promising data ATIR studies presented by NIH Investigators

Amsterdam, November 28, 2007- Kiadis Pharma announced today the presentation of the results obtained so far in the physician initiated study led by Dr. Stephan Mielke\* and Dr. John Barrett\* of the National Heart, Lung, and Blood Institute (NHLBI) a department of the National Institutes of Health (NIH) on Kiadis' lead product ATIR at the AABB annual meeting & TXPO 2007 in Anaheim, California.

According to the NHLBI investigators the challenge in the field of allogeneic bone marrow transplantations lies with disease control, Graft versus Host Disease (GvHD) control and donor availability. Doctors Barrett and Mielke have focused on controlling GvHD whilst sparing the Graft versus Leukemia (GvL) effect and also on increasing donor availability.

The investigators have published the preclinical data showing promising results with Kiadis Pharma's ATIR in eliminating alloreactive T cells from donor grafts (Mielke et al. Blood, 2007). These results have led to the start of a phase II study with ATIR by the NHLBI. This trial is designed to demonstrate that ATIR treatment may overcome the need of immunosuppressant prophylaxis post transplantation. Prophylaxis is currently standard practice to prevent GvHD, but has a serious drawback, as it increases the chance of infection and also the relapse rate. Thus ATIR does not only intend to prevent GvHD, but could also reduce the rates of infection and relapse. Together, these complications account for approximately 70 % of allogeneic transplant related mortality.

For the clinical study the NHLBI investigators developed a reliable large scale manufacturing protocol with a "GMP-like" semi-closed system for cell processing with ATIR. The ongoing phase II study is performed with this semi-closed cell processing system. The first three patients have successfully been treated with ATIR. The preliminary results are promising, demonstrating technical feasibility and no acute GVHD in the patients treated so far. An early donor-dominated immune cell chimerism was observed; an indication for the functionality of the ATIR treated immune cells. Although still early, none of these high-risk cancer patients relapsed to date.

ATIR selectively eliminates those immune cells that could otherwise attack the patient's body after an allogeneic bone marrow transplantation and cause GvHD. Eliminating this risk could improve the outcome of current allogeneic transplantations and, moreover, could overcome the donor selection barrier and allow the use of mismatched donors. Kiadis Pharma's ATIR product was already under evaluation in two "mismatched donor" trials. The clinical phase II study by NHLBI has now extended the use of ATIR in an HLA-**matched** transplant

### 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 high-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](http://www.kiadis.com)

**\*Note**

Dr John Barrett is the Chief of the Allotransplant Section at the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) in Bethesda, MD, USA, where the trial is being performed. Dr Stephan Mielke, who initiated this study as principal investigator at the NHLBI, is currently working at the Julius-Maximilians University of Würzburg, Germany and continues as the lead associate investigator on the protocol.

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