



## **Kiadis Pharma receives Orphan Drug Designation for Rhitol™ from the FDA**

**Amsterdam, April 15, 2008** – Biopharmaceutical company Kiadis Pharma announced today that the U.S. Food and Drug Administration (FDA) has granted its product Rhitol™ Orphan Drug Designation for the treatment of chronic Graft versus Host Disease (GvHD). This complication of allogeneic bone marrow transplantation is highly debilitating and can become life threatening when the patient is unresponsive to steroid treatment. Rhitol™ has completed a multicenter phase I/II study for patients with severe steroid resistant chronic GvHD. A phase III study is anticipated to start in 2008.

*"The decision by the FDA to grant Rhitol™ orphan drug designation in this area of blood cancer with unmet medical need advances our efforts to develop an innovative treatment"* says 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 United States after product approval.

### **About Rhitol™**

Rhitol™ is under development as a treatment for patients with chronic GvHD resistant or intolerant to immunosuppressive agents. Rhitol™ treatment targets activated T cells that cause GvHD and results in immune modulation within patients with chronic GvHD, restores immune tolerance and attempts to achieve disease remission.

### **About chronic GvHD**

GvHD is a condition that can develop after allogeneic bone marrow transplantation and resembles an autoimmune disease. Graft versus Host Disease is caused by immune cells from the donor graft attacking the patient's tissues and organs. Chronic GvHD usually develops some time after the transplantation and is generally treated by immunosuppressive drugs, such as steroids. The disease can however become life threatening when standard treatment cannot control its progression and the patient does not respond to additional immunosuppressive treatment or develops severe side effects to their use. Patients with extensive chronic GvHD have multiple organs and tissues affected and in general have a very poor quality of life.

### **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 blood cancer products in different phases of clinical development that offer novel treatment options for terminally ill 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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