Kiadis Pharma presents positive data on the primary endpoint of its single dose Phase II trial with ATIR101™

~ Significant increase in Overall Survival and reduction in Transplant Related Mortality observed in comparison to a historical control group ~
~ Zero patients developed grade III-IV acute Graft-versus-Host-Disease upon infusion of ATIR101™ ~
~ Initiation of a randomised Phase III trial in the second half of 2016 ~
~ Management will host a webcast to discuss the data today at 18.00 CET ~

Amsterdam, The Netherlands, April 4, 2016, – Kiadis Pharma N.V. **("Kiadis Pharma" or the "Company") (Euronext Amsterdam and Brussels: KDS)**, a clinical stage biopharmaceutical company developing innovative T-cell immunotherapy treatments for blood cancers and inherited blood disorders, today presents positive results on the primary endpoint of its single dose Phase II trial (NCT01794299/EudraCT 2012-004461-41) with its lead product ATIR101™ at the 42nd Annual Meeting of the European Society of Blood and Marrow Transplantation (EBMT) in Valencia, Spain.

The data presented in session O042 by Dr. Denis-Claude Roy, Professor of Medicine at the University of Montreal and the principal investigator for the trial, confirms that ATIR101™ can be safely infused, does not cause grade III-IV Graft-versus-Host-Disease (GVHD) and shows a significant reduction in Transplant Related Mortality (TRM) and a significant improvement in Overall Survival (OS) in comparison to a historical control group of patients undergoing a T-cell depleted haploidentical donor transplantation only.

Trial details
Twenty-three leukaemia patients with a median age of 41 years (range 21-64) were enrolled into and treated on this trial from sites in Canada, Belgium, Germany and the United Kingdom. Patients were eligible for an allogeneic hematopoietic stem cell transplantation (HSCT) but could not find a matching donor in time. Sixteen patients had acute myeloid leukaemia (AML) and seven had acute lymphoblastic leukaemia (ALL). Patients were either in first or second complete remission at the time of the HSCT and the majority of patients (57%) had a poor prognosis based on their disease risk index and cytogenetic profile. A myeloablative conditioning regimen was used and (haploidentical) donor grafts were depleted of T-cells (CD34+ selection) prior to transplantation. Patients engrafted rapidly (median 12 days) and ATIR101™ was subsequently infused at a fixed dose of $2x10^6$ CD3+ cells/kg at a median of 28 days post-transplant.

The median follow-up, on March 24, 2016, was 414 days (range 110 – 742) post-HSCT, at which point all patients were beyond six months post-HSCT, allowing assessment of the primary endpoint of this trial, which is TRM at six months. Patients will be continued to be followed in order to collect further long-term outcome data.

No patients (0/23) developed grade III-IV GVHD upon infusion of ATIR101™, confirming the efficacy of the elimination of allo-reactive T-cells from ATIR101™. Three cases of grade II acute

GVHD were reported; one case developed before ATIR101™ infusion and the other two cases had a delayed onset, at day 173 and day 247 post-HSCT (145 and 219 days post ATIR101™ infusion) respectively. In the patient who developed GVHD before ATIR101™ infusion, GVHD resolved quickly and subsequently ATIR101™ was infused, not triggering any further GVHD.

The primary endpoint of the trial is TRM within six months post-HSCT. Overall, three cases of TRM were reported within the first six months post-HSCT, giving a TRM rate of 13%. In all cases the cause of death was an infection. No mortality was observed within the first 100 days post-HSCT. In addition to the three TRM cases, only one patient died as a result of disease relapse within the first six months, resulting in an Overall Survival of 83%.

When compared to a historic control group (N=35) consisting of patients matching the inclusion and exclusion criteria of the Company's Phase II trial who underwent a similar HSCT procedure from haploidentical family members but without the addition of ATIR101™, TRM was significantly lower (p=0.005) in patients who were given ATIR101™ after a T-cell depleted haploidentical transplantation. The six month TRM for HSCT + ATIR101™ is 13% versus 37% for HSCT only.

Disease relapse in the trial was limited, with only two patients developing disease relapse within the first 12 months after HSCT (at day 61 and 90 post HSCT respectively). Combined with the reduced rate of TRM, this translates into a significantly improved OS (p=0.0026) of patients undergoing HSCT + ATIR101™ compared to patients undergoing HSCT only. Based on the Kaplan-Meier estimates, the one-year survival in the HSCT + ATIR101™ group was 64% compared to only 20% in the historic control group.

Based on the positive results from this Phase II trial, the Company will proceed with the development of ATIR101™ as an adjunctive immuno-therapeutic treatment to a haploidentical HSCT for patients with acute leukaemia, initiating a randomised Phase III trial in the second half of 2016. In addition, the Company will discuss the opportunity for potential conditional (accelerated) approval of ATIR101™ with the regulatory authorities.

Manfred Rüdiger, PhD, Chief Executive Officer of Kiadis Pharma, commented: *"We are very excited about the strong and compelling results from our Phase II trial. The data shows substantially improved Overall Survival rates and low Transplant Related Mortality. In addition, with the infusion of ATIR101™, no incidents of life threatening grade III-IV GVHD were detected, despite patients not receiving any prophylactic immune-suppressants. We believe that our ATIR101™ approach compares very favourably with the post-transplant cyclophosphamide protocols pioneered in Baltimore. Having no grade III-IV GVHD and very low relapse rates makes us believe that ATIR™ will become an attractive alternative for patients who don't have a matching donor. We are looking forward to the initiation of the randomised Phase III international controlled trial, comparing our ATIR101™ approach directly to the Baltimore approach. The data also provides a solid base for discussions with regulatory authorities concerning potential early market approval of ATIR101™."*

Dr. Denis-Claude Roy, Professor of Medicine at the University of Montreal and one of the

principal investigators for the trial, added: *"With this latest data we can confirm the safety of ATIR101™, without any incidents of grade III-IV GVHD, significant reduction in Transplant Related Mortality, low relapse rates and very good event free survival, which we believe confirms the efficiency of photodepletion-based elimination of allo-reactive T-cells. Indeed, the data of patients receiving transplants with a haploidentical donor and an ATIR101™ infusion are very similar to those from patients with a matched donor. As a doctor, I am very excited about this development and its potential to change patient fates."*

Webcast

Manfred Rüdiger, Chief Executive Officer and Jeroen Rovers, Chief Medical Officer, together with Dr. Denis-Claude Roy, Professor of Medicine at the University of Montreal and principal investigator for the trial, will host a webcast to discuss the data today at 18.00 CET.

To register for the webcast, please visit the homepage of Kiadis Pharma at: www.kiadis.com.

To listen to the webcast, please call the appropriate number below, 10 minutes prior to the start time:

The Netherlands:	020 716 8427
Toll-free The Netherlands:	0800 265 8619
Belgium:	02 401 2722
Toll-free Belgium:	0800 50 562
United Kingdom:	0203 139 4830
Toll-free United Kingdom:	0808 23 700 30
United States:	1718 873 9077
Toll-free United States:	1866 928 7517

Conference ID: 25282024#

The webcast will be conducted in English and viewers will have the opportunity to submit questions during the Q&A portion of the live webcast. A replay of the webcast will be made available on Kiadis Pharma's website.

About ATIR101™

For patients suffering from blood cancers, an allogeneic hematopoietic stem cell transplantation (HSCT) is generally regarded as the most effective curative approach. During an HSCT treatment, the bone marrow, harbouring the diseased cancer cells, is completely destroyed and subsequently replaced by stem cells in the graft from a healthy donor. After an HSCT treatment it usually takes the patient at least six to twelve months to recover to near-normal blood cell levels and immune cell functions. During this period, the patient is highly vulnerable to infections caused by bacteria, viruses and fungi but also to disease relapse.

ATIR101™ (Allodepleted T-cell ImmunotheRapeutics) provides for a safe donor lymphocyte infusion (DLI) from a partially matched (haploidentical) family member without the risk of causing severe Graft-versus-Host-Disease (GVHD). The T-cells in ATIR101™ will help fight

infections and remaining tumour cells and thereby bridge the time until the immune system has fully re-grown from stem cells in the transplanted graft.

In ATIR101™, T-cells that would cause GVHD are eliminated from the donor lymphocytes using Kiadis Pharma's photodepletion technology, minimizing the risk of GVHD and eliminating the need for prophylactic immune-suppression. At the same time, ATIR101™ contains potential cancer killing T-cells from the donor that could eliminate residual cancer cells and help prevent relapse of the disease, known as the Graft-versus-Leukaemia (GVL) effect.

Therefore, ATIR101™, administered as an adjunctive immuno-therapeutic on top of HSCT, provides the patient with functional, mature immune cells from a partially matched family donor that can fight infections and tumour cells but that do not cause GVHD. ATIR101™ thus has the potential to make curative HSCT a viable option to many more patients.

The Company estimates that approximately 35% of patients who are eligible and in urgent need of HSCT will not find a matching donor in time. A partially matched (haploidentical) family donor, however, will be available to over 95% of patients.

ATIR101™, consisting of donor T-cells that fight infections and residual tumour cells while not eliciting severe GVHD, is designed to result in low relapse rates and low rates of death due to infections, in the absence of severe acute GVHD.

About Kiadis Pharma

Kiadis Pharma is a clinical stage biopharmaceutical company focused on research, development and future commercialization of cell-based immunotherapy products for the treatment of blood cancers and inherited blood disorders. The Company believes that its innovative products have the potential to address the current risks and limitations connected with allogeneic hematopoietic stem cell transplantation (HSCT), being graft-versus-host disease (GVHD), cancer relapse, opportunistic infections and limited matched donor availability. HSCT is generally regarded as the most effective curative approach to blood cancers and certain inherited blood disorders and the Company expects that HSCT could become a first-choice treatment for blood cancers and inherited blood disorders once current risks and limitations are addressed, thereby meeting a significant unmet medical need with its products.

The Company's product ATIR101™ is being tested using a single-dose regimen in an open-label fully enrolled Phase II trial in patients with blood cancer who have not found a matching donor and where a partially matched (haploidentical) family member is used as donor for HSCT. The primary endpoint for the final patient in this trial will be reached at the end of Q1, 2016 and top-line results will be announced in April 2016. Very encouraging and positive interim data of this trial was presented recently at ASH2015.

In addition, the Company is enrolling blood cancer patients in a further Phase II clinical trial to study the safety and efficacy of administrating a second dose of ATIR101™ to further improve the HSCT outcome.

The European Medicines Agency (EMA) has issued an Advanced Therapy Medicinal Product (ATMP) certificate for manufacturing quality and non-clinical data to the Company, and to date Kiadis Pharma is one of only five companies that have received such a certificate.

ATIR101™ has been granted Orphan Drug Designations both in the US and Europe.

ATIR201™ will be developed for inherited blood disorders with an initial focus on thalassaemia, an inherited blood disorder which results in improper oxygen transport and destruction of red blood cells in a patient. ATIR201™ is expected to enter Phase I/II clinical development for thalassaemia in the first quarter of 2016. Kiadis Pharma recently announced a collaboration with the Thalassaemia International Federation (TIF), an internationally renowned organisation that seeks to address the needs of patients, carers, healthcare professionals and the general public in the area of thalassaemia.

Kiadis Pharma is based in Amsterdam, the Netherlands and its shares are listed on Euronext Amsterdam and Euronext Brussels. Further information can be found at: www.kiadis.com

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