Kiadis Pharma presents positive 1-year follow-up data of its pivotal Phase II trial with ATIR101™

~ Significant reduction in Transplant Related Mortality and improvement in Overall Survival observed in comparison to an observational control group ~
~ Zero patients developed grade III-IV acute Graft-versus-Host-Disease upon infusion of ATIR101™ ~

Amsterdam, The Netherlands, December 6, 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 one-year data with its lead product ATIR101™ from the single dose Phase II trial (NCT01794299/EudraCT 2012-004461-41) at the 58th Annual Meeting and Exposition of the American Society of Hematology (ASH) in San Diego, United States of America.

The data presented at ASH in session 711 by Dr. Denis-Claude Roy, Professor of Medicine at the University of Montreal, one of the principal investigators for the trial and protocol chair, confirms that ATIR101™ can be safely infused and shows a significant reduction in Transplant Related Mortality (TRM) (primary endpoint) and a significant improvement in Overall Survival (OS) (secondary endpoint) in comparison to an observational control group of patients undergoing a T-cell depleted haploidentical donor transplantation only. Combined with the lack of severe Graft-versus-Host-Disease (GVHD) and limited relapse, this translates into favorable GVHD-free, relapse-free survival (GRFS) one-year post-transplantation.

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. Looking at the GRFS endpoint, a composite endpoint used to present outcome data, our ATIR101™ approach compares very favorably with the post-transplant cyclophosphamide protocols pioneered in Baltimore. Having no grade III-IV GVHD and very low relapse rates makes us believe that ATIR101™ could become an attractive alternative for patients who don't have a matching donor. We will submit a Marketing Authorization Application to the European Medicines Agency (EMA) for our data in the first quarter of 2017 and our next immediate step is the initiation of our transatlantic randomized Phase III international controlled trial, comparing our ATIR101™ approach directly to the Baltimore approach."*

Dr. Denis-Claude Roy, Professor of Medicine at the University of Montreal, one of the principal investigators for the trial and protocol chair, 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. As a doctor, I am very excited about this development and its potential to change patient fates."

Trial details

Twenty-three leukemia 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 leukemia (AML) and seven had acute lymphoblastic leukemia (ALL). Patients were either in first or second complete remission at the time of the HSCT. The majority of patients had a poor prognosis based on their Disease Risk Index (DRI) (57% high/very high risk), while the remaining 43% had an intermediate risk index. A myeloablative conditioning regimen was used and (haploidentical) donor grafts were depleted of T-cells (CD34+ selection) prior to transplantation. Patients engrafted rapidly (median twelve days) and ATIR101™ was subsequently infused at a fixed dose of $2x10^6$ CD3+ cells/kg at a median of 28 days post-transplant without use of any post-transplant GVHD prophylaxis.

The median follow-up, on November 28, 2016, was 485 days (range 110-742) post-HSCT, at which point all patients were beyond one year post-HSCT.

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™. Only three cases of grade II acute GVHD were reported after infusion of ATIR101™. In addition, one case of chronic GVHD was reported after infusion of ATIR101™.

Despite the fact that the majority of patients were at high risk for relapse (DRI-high) only two patients developed disease relapse within the first twelve months after HSCT (at day 61 and day 90 post-HSCT respectively). No mortality was observed within the first 100 days post-HSCT. Nine patients died within the first year after transplantation, seven due to TRM and two due to disease relapse, resulting in a one-year OS of 61%.

When compared to control data from an observational cohort study (consisting of a group of 35 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™), OS was significantly higher (p=0.003) in patients who were given ATIR101™ after a T-cell depleted haploidentical transplantation. The one-year OS for HSCT + ATIR101™ is 61% versus 20% for HSCT only. TRM was significantly lower (p=0.007), the one-year TRM for HSCT + ATIR101™ being 32% versus 70% for HSCT only.

GRFS, defined as patients surviving without getting severe acute GVHD (grade III-IV) or chronic GVHD (requiring systemic treatment) and without relapsing, for patients treated with HSCT and an adjuvant infusion of ATIR101™ was 57% at one year. This compares favorably with patients in the contemporaneous observational control group undergoing an HSCT only (with GRFS at 20%) and also with patients in that same control group receiving a Matched Unrelated Donor transplantation (HLA 8/8 or 10/10 match), where the GRFS at one year is 41%. Compared to reported GRFS data for haploidentical transplants done using the post-transplant cyclophosphamide (PTCy) approach to control GVHD, the GRFS of 57% at one year for the HSCT + ATIR101™ group is favorable to the GRFS of 33% reported for the PTCy group (Solh et al, BBMT 2016).

Patients will continue to be followed-up until two years post-HSCT in order to collect further long-term outcome data. Out of the 23 patients enrolled in the trial, five have already completed the full two year follow-up alive and four patients are still alive on study. The final data from this trial will be available in the second half of 2017.

Based on the positive results from this Phase II trial, the Company is proceeding with the development of ATIR101™ by initiating a Phase III trial in which patients with acute leukemia will be randomized to receive a haploidentical HSCT according to either the PTCy approach or the Kiadis Pharma approach with a single dose of ATIR101™. This Phase III trial has been submitted to regulatory authorities and is currently under review for approval.

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, harboring 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 tumor 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-Leukemia (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 tumor 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 tumor 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 focused on cell-based immunotherapy products for the treatment of blood cancers and inherited blood disorders. The Company's products have the potential to address

the risks and limitations connected with allogeneic hematopoietic stem cell transplantation (HSCT), namely Graft-versus-Host-Disease (GVHD), cancer relapse, opportunistic infections and limited matched donor availability. The Company believes that HSCT could become a first-choice treatment for blood cancers, inherited blood disorders and possibly autoimmune diseases and solid organ transplantations.

In April 2016, the Company reported positive Phase II results with its lead product ATIR101™ in patients with blood cancer. The data showed that ATIR101™ significantly reduced Transplant Related Mortality and significantly improved Overall Survival. In addition, ATIR101™ did not elicit grade III-IV GVHD in any patient. ATIR101™ has been granted Orphan Drug Designations both in the US and Europe. The Company's second product candidate, ATIR201™, addresses inherited blood disorders with an initial focus on thalassemia, a disease which results in destruction of red blood cells in patients. ATIR201™ is expected to enter Phase I/II clinical development in the second half of 2016.

Kiadis Pharma, based in Amsterdam, The Netherlands, was granted an Advanced Therapy Medicinal Product (ATMP) certificate for manufacturing quality and non-clinical data by the European Medicines Agency (EMA). The Company's shares are listed on Euronext Amsterdam and Euronext Brussels. For more information visit www.kiadis.com

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