



Kiadis Pharma issues clinical and regulatory progress update on ATIR101™ and ATIR201™

~ Pivotal Phase III trial with ATIR101™ initiated ~

~ MAA submission to EMA for ATIR101™ progressing well ~

Amsterdam, The Netherlands, February 6, 2017, – 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 provides a progress update on the clinical and regulatory status of ATIR101™, the Company’s lead product to address the key risks and limitations of hematopoietic stem cell transplantation (HSCT) in blood cancer.

Initiation of pivotal Phase III trial with ATIR101™

Following regulatory approval from the national authority in Canada (Health Canada), the Company is pleased to announce the initiation of its randomized, controlled, transatlantic Phase III trial with ATIR101™ (CR-AIR-009). Approximately 195 patients with acute leukemia will be enrolled in total in the Phase III trial and randomized 1:1 to receive a haploidentical allogeneic HSCT using either the Kiadis Pharma approach with a single dose of ATIR101™ or the post-transplant cyclophosphamide approach (also known as the Baltimore Protocol). The trial protocol has also been submitted for approval and is being evaluated by the United States FDA (Food and Drug Administration) as well as several European regulatory authorities. Following approval the trial will be rolled out to additional study centers in the United States and Europe.

CTI Clinical Trial and Consulting Services, Inc., an international clinical contract research organization, has been appointed to work with Kiadis Pharma to support the clinical part of the trial and PCT, LLC, A Caladrius Company, a leading external manufacturing partner to the cell therapy industry, will manufacture ATIR101™ for the United States and Canada. The German Red Cross Blood Donor Service, Baden-Wuerttemberg-Hessen, will remain the manufacturer in Europe. All 15 study centers that participated in the Company’s Phase II trials with ATIR101™ (CR-AIR-007 and CR-AIR-008) have confirmed their intention to participate in the Phase III trial (CR-AIR-009). Kiadis Pharma is actively and rapidly aligning more sites with the aim of having more than 40 sites in North America and Europe participating in the Phase III trial.

Ongoing CR-AIR-008 trial continues to confirm safety profile of ATIR101™

Infusing a single dose of ATIR101™ continues to be safe in the ongoing Phase II trial with ATIR101™ (CR-AIR-008) which, as previously announced, is continuing to treat patients with a single dose of ATIR101™ according to the clinical protocol and the recommendation of the Independent Data Monitoring Committee (IDMC). Five patients in this trial have now been treated with a single dose of ATIR101™ of which three were infused more than 120 to 150 days ago. None of these patients have shown any symptoms of severe Graft-versus-Host-Disease (GVHD), with none having received any prophylactic immunosuppression.

MAA submission to EMA for ATIR101™ progressing well

Following the Company's decision to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for the use of ATIR101™ in blood cancers, Kiadis Pharma confirms that the preparations for submitting the dossier are progressing well. The MAA will be based on the results from the Company's successful single dose Phase II trial (CR-AIR-007) which confirmed that ATIR101™ can be safely infused and shows statistically significant benefits on overall survival and reducing death from GVHD and infections, compared to an observational control group of patients having received a similar T-cell depleted stem cell transplant from a haploidentical family member but without the addition of ATIR101™.

Kiadis Pharma has previously received an Advanced Therapy Medicinal Product (ATMP) certificate from EMA for manufacturing quality and pre-clinical data, recognizing that this data generated for ATIR101™ meets the stringent standards imposed by the agency in evaluating an MAA.

Contingent on approval from EMA, Kiadis Pharma anticipates launching ATIR101™ in to the European market in 2018.

Phase I/II trial with ATIR201™

As previously announced, the Company's Phase I/II clinical trial with its product ATIR201™ for thalassemia (CR-BD-001) has received regulatory approval from the national authority in the United Kingdom (the MHRA, the Medicines and Healthcare products Regulatory Agency) as well as approval from the Ethics Committees of the Royal Manchester Children's Hospital and the Birmingham Children's Hospital. In addition, approval from the Ethics Committee of the University of Regensburg in Germany has now been received, with regulatory approval from the national authority in Germany pending. Kiadis Pharma expects the first clinical trial data to become available in the second half of 2017.

Manfred Rüdiger, PhD, Chief Executive Officer of Kiadis Pharma, commented: *"I am very excited that we have initiated our pivotal Phase III trial with ATIR101™. We have significant momentum now and the preparation of our MAA submission to EMA is progressing well. This work will bring our potentially life-saving treatment, which is also protected by Orphan Drug Designations in both Europe and the US, one step closer to patients with an anticipated launch in Europe in 2018."*

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 Immunotherapy) 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.

On December 5, 2016 at the Annual Meeting of the American Society of Hematology (ASH), 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. Based on these positive results, a Phase III clinical trial has been initiated. 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™ Phase I/II clinical development has been initiated recently.

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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