



Kiadis Pharma announces its decision to file for marketing authorization with the European Medicines Agency (EMA) for ATIR101™ in blood cancers

~ Regulatory strategy update ~

Amsterdam, The Netherlands, June 2, 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 announces a regulatory strategy update that, based on positive Phase II data, it has taken the decision to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for its lead product ATIR101™ for use in blood cancers to reduce relapse rates, Transplant Related Mortality (TRM) and Graft-versus-Host-Disease (GVHD) in the context of a hematopoietic stem cell transplantation using a haploidentical donor. The Company will now start compiling an MAA document and anticipates submitting the application to EMA in Q1, 2017.

An EMA rapporteur and co-rapporteur (who will jointly co-ordinate the evaluation of Kiadis Pharma’s MAA submission) were appointed in early 2015. In addition, in April 2015 Kiadis Pharma received a certificate for its (manufacturing) quality and non-clinical data from EMA.

Positive clinical data from Kiadis Pharma’s single dose Phase II trial (NCT01794299/EudraCT 2012-004461-41) with ATIR101™ was announced on April 4, 2016 at the Annual Meeting of the European Society of Blood and Marrow Transplantation (EBMT) in Valencia, Spain. The data showed that ATIR101™ significantly reduced TRM and significantly improved Overall Survival in comparison to a historical control group of patients that underwent a similar T-cell depleted haploidentical donor transplantation but without the addition of ATIR101™. In addition, ATIR101™ did not elicit grade III-IV GVHD in any patient.

Recently, meetings were held with the EMA rapporteur and co-rapporteur during which Kiadis Pharma presented safety and manufacturing data as well as clinical data from this Phase II trial, a trial that was designed on the basis of scientific advice previously given by EMA.

Manfred Rüdiger, PhD, Chief Executive Officer of Kiadis Pharma, commented: *“We are excited about the progress we have made with ATIR101™ over the past year. The Company is again entering into a new phase in its development as we are starting preparations for commercialization. The submission of an MAA in Q1, 2017 was our ambitious upside-plan communicated at the time of our IPO, now a year ago, and we are moving nicely ahead with good momentum. A launch of ATIR101™ in Europe could be possible as early as 2018 if marketing authorization is granted by EMA. We are also fully committed to starting the enrollment of patients into our planned randomized, international controlled Phase III trial where we will compare the ATIR101™ approach with post-transplant cyclophosphamide (Baltimore approach) in the context of haploidentical transplantation. I look forward to the*

future with tremendous excitement in this next phase.”

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.kiadispharma.com

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