

# Kiadis Pharma Interim Management Statement for the nine months ended 30 September 2015

Amsterdam, The Netherlands, November 27, 2015 – 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 its Interim Management Statement for the nine months ended 30 September 2015.

#### **Operational review**

Kiadis Pharma continued to make good progress in developing its lead product ATIR101™ for blood cancer:

- Full enrolment of the ongoing Phase II clinical study (CR-AIR-007) with ATIR101™ has been accomplished. The primary endpoint for the last patient in this trial will be reached at the end of Q1, 2016 and top-line results will follow at the beginning of Q2, 2016.
- Another study (CR-AIR-008), testing repeat dose administration of ATIR101™ in parallel with the ongoing Phase II trial, has been initiated and has enrolled its first patient.
- Establishing a closed manufacturing process that allows for automation which is advancing according to plan.

#### Interim financial results

In the first nine months of 2015, the Company did not generate any revenues. The net loss for the nine months ended 30 September 2015 came at a level of €13.1 million. Expenses and net results are in line with management expectations. The Company ended the first nine months of 2015 with €31.3 million in cash and cash equivalents and an equity position of €29.1 million.

Kiadis Pharma listed its shares via an IPO on Euronext Amsterdam and Brussels on 2 July 2015. The gross proceeds from the IPO came to a total of €34.7 million and net proceeds came to a total of €31.2 million.

The financial information in this press release has not been audited nor reviewed by the external auditor.

#### **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, minimising 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 commercialisation 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.

Currently, the Company's product ATIR101™ is being tested using a single dose regimen in an open-label 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. Kiadis Pharma announced full enrolment of this trial in July 2015. The primary endpoint for the last patient in this trial will be reached at the end of Q1, 2016, top-line results to follow at the beginning of Q2, 2016.

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.

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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# Forward Looking Statements

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