



## **Kiadis Pharma announces filing of marketing authorization with the European Medicines Agency for ATIR101™ in blood cancers**

Amsterdam, The Netherlands, April 26, 2017 – Kiadis Pharma N.V. (“Kiadis Pharma” or the “Company”) (Euronext Amsterdam and Brussels: KDS), a clinical stage biopharmaceutical company developing innovative products to make bone marrow transplantations for patients suffering from blood cancers and inherited blood disorders safer and more effective, today announces it has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for its lead product, ATIR101™. The Company is seeking marketing approval in the European Union for ATIR101™ as an adjunctive treatment in haematopoietic stem cell transplantation (HSCT) for malignant disease.

The filing is based on Kiadis Pharma’s existing clinical data and follows positive interactions with the EMA Rapporteur and Co-Rapporteur which indicated support for the filing using the Company’s single dose Phase II trial with ATIR101™ as the pivotal study. The Company submitted the application under the European Union’s centralized procedure, which permits the agency to issue a single marketing authorization that is valid across all EU countries.

**Arthur Lahr, Chief Executive Officer of Kiadis Pharma, commented:** *“Submission of this MAA to the EMA marks a pivotal point in Kiadis Pharma’s development and brings us a significant step closer towards commercializing our lead product ATIR101™ for the treatment of blood cancer, across the EU. The data generated thus far for ATIR101™ has been very positive and we are optimistic that we will receive a positive outcome from the EMA during the second half of 2018, allowing us to make ATIR101™ available to transplantation centers across the EU in 2019. It is a great achievement that Kiadis Pharma has reached this milestone on its own merit, which only a very few biotech companies accomplish, and it is testament to the strength of the unique data and of the Kiadis Pharma organization.”*

Positive and significant results from Kiadis Pharma’s single dose Phase II trial with ATIR101™ were reported on December 5, 2016 at the Annual Meeting of the American Society of Hematology (ASH). The data showed that ATIR101™ significantly improved overall survival compared to a historical matched control. In addition, relapse and Graft-versus-Host-Disease (GVHD) rates were significantly lower than those reported for alternative approaches for HSCT. Specifically, ATIR101™ did not elicit acute grade III-IV GVHD in any patient.

### **About ATIR101™**

For patients suffering from blood cancers and inherited blood disorders, an allogeneic hematopoietic stem cell transplantation (HSCT) is generally regarded as a potentially curative approach. During an HSCT treatment, the patient’s diseased blood and immune system are destroyed and subsequently replaced by a healthy system from a donor. The treatment is, however, very risky as it usually takes the patient at least six to twelve months to recover to near-normal immune cell functions, making patients highly vulnerable to infections and

disease relapse. Mature lymphocytes in the donor graft would provide immediate protection, but, depending on the level of genetic mismatch between patient and donor, may cause life threatening Graft-versus-Host-Disease (GVHD).

The Company estimates that approximately 35% of patients who are eligible and in urgent need of an HSCT will not find an adequately matched donor in time. A half-matched (haploidentical) parent or child, however, could serve as a donor for nearly all patients, yet would cause severe GVHD due to the infusion of half-matched mature lymphocytes. The therapy Kiadis Pharma is developing would enable the use of haploidentical transplants without the unacceptable risk of GVHD.

ATIR101™ (Allodepleted T-cell Immunotherapeutics) provides for a safe single dose donor lymphocyte infusion (DLI) with functional, mature immune cells from a haploidentical family member with minimal risk of causing severe GVHD. ATIR101™ will help fight infections and remaining tumor cells and thereby bridge the time until the patient's immune system has fully re-grown from stem cells in the transplanted graft.

### **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 product candidates, ATIR101™ for blood cancers and ATIR201™ for inherited blood disorders, have the potential to make allogeneic hematopoietic stem cell transplantations (HSCT) safer and more effective.

Based on the significant and positive results from the single dose Phase II trial with lead product ATIR101™ in patients with blood cancer, which were presented on December 5, 2016 at the Annual Meeting of the American Society of Hematology (ASH), the Company has initiated a Phase III trial with ATIR101™, having received regulatory approval in various countries to start dosing patients. In addition, and based on the positive Phase II results, the Company has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for approval of ATIR101™ across Europe as an adjunctive treatment in HSCT for malignant disease. 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. ATIR201™ Phase I/II clinical development has been initiated recently with regulatory approvals having been received in various European countries to start the trial.

Kiadis Pharma was granted an Advanced Therapy Medicinal Product (ATMP) certificate for manufacturing quality and non-clinical data by the EMA. The Company's shares are listed on Euronext Amsterdam and Euronext Brussels. For more information visit [www.kiadis.com](http://www.kiadis.com)

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**Forward Looking Statements**

*Certain statements, beliefs and opinions in this press release are forward-looking, which reflect Kiadis Pharma's or, as appropriate, Kiadis Pharma's directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, Kiadis Pharma expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither Kiadis Pharma nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.*