



### **Last patient dosed with ATIR101™ in the Phase II '008' clinical trial**

- **Results from the single dose 1-year follow up consistent with prior Phase II study**
- **Data supports already submitted marketing authorization application**

**Amsterdam-Duivendrecht, The Netherlands, January 31, 2018 – Kiadis Pharma N.V. (“Kiadis Pharma” or the “Company”) (Euronext Amsterdam and Brussels: KDS),** a clinical stage biopharmaceutical company developing innovative T-cell therapy products aiming to make bone marrow transplantations safer and more effective for patients, today announces that the last patient in the Phase II CR-AIR-008 ('008') trial has received a single dose of ATIR101™.

This exploratory Phase II trial (clinicaltrials.gov identifier: NCT02500550) was designed to evaluate the safety and efficacy of two doses of ATIR101™ in patients with a hematologic malignancy who received a hematopoietic stem cell transplantation from a haploidentical (half-matched) donor.

A total of 15 patients were recruited into the trial. Six of these patients received two doses of ATIR101™ before the independent data monitoring committee (IDMC) recommended that the trial should continue treating patients with one dose of ATIR101™ (announced on December 21, 2016). The remaining nine patients on the trial have now been treated with a single dose of ATIR101™. Of these nine patients, five patients are 1-year post treatment and results are consistent with the previously conducted 23-patient CR-AIR-007 single dose Phase II trial.

**Arthur Lahr, CEO of Kiadis Pharma, commented:** *“We are pleased to have completed enrollment into this Phase II study and can now fully focus on enrollment of the Phase III study. The single dose 1-year results from this study further increase and support the data in the marketing authorization application (MAA) we submitted to the European Medicines Agency (EMA) in April 2017. The Company remains on track to potentially obtain (conditional) EMA approval for ATIR101™ in Q4 2018 which would allow for a European launch in H2 2019.”*

#### **About Kiadis Pharma**

Kiadis Pharma's allodepleted T-cell immunotherapy product can make haploidentical hematopoietic stem cell transplantations (HSCT) safer and more effective. Single dose Phase II data with lead product ATIR101™ given after an HSCT in patients with blood cancer shows a strong and clinically very relevant improvement over literature for the Baltimore protocol, without the risk of severe chronic Graft versus Host Disease (GVHD). Based on the positive results from the CR-AIR-007 single dose Phase II trial, the Company submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in April 2017, for approval of ATIR101™ across the EU as an adjunctive treatment in HSCT for malignant disease. Kiadis Pharma received Day 120 questions in September 2017 and is on track for potential (conditional) approval in Q4 2018 and launch in H2 2019. Kiadis Pharma is conducting a Phase III trial with ATIR101™ across Europe and North America (head to head against the Baltimore protocol). The first patient was enrolled in December 2017.

In September 2017 the US Food and Drug Administration (FDA) granted ATIR101™ the Regenerative Medicine Advanced Therapy (RMAT) designation. ATIR101™ has been granted Orphan Drug Designations both in the US and Europe.

The Company's shares are listed on Euronext Amsterdam and Brussels under the ticker KDS.

Website: [www.kiadis.com](http://www.kiadis.com)

Company presentation: [www.kiadis.com/company-presentation/](http://www.kiadis.com/company-presentation/)

**For more information, please contact:**

**Kiadis Pharma:**

Karl Hård

Head of IR & Communications

Tel. +31 611 096 298

[k.hard@kiadis.com](mailto:k.hard@kiadis.com)

or

**Consilium Strategic Communications:**

Mary-Jane Elliott, Philippa Gardner, Lindsey Neville, Hendrik Thys

Tel: +44 203 709 5708

[kiadis@consilium-comms.com](mailto:kiadis@consilium-comms.com)

**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.*