# Kiadis Submits Response to the European Medicines Agency's Day 180 Second List of Outstanding Issues

Amsterdam, The Netherlands, May 22, 2019 - Kiadis Pharma N.V. ("Kiadis Pharma" or the "Company") (Euronext Amsterdam and Brussels: KDS), a clinical-stage biopharmaceutical company, today announced that it has submitted a response to the European Medicines Agency's (EMA) second Day 180 list of outstanding issues for ATIR101. Kiadis submitted a marketing authorization application (MAA) to the EMA in 2017 seeking approval of ATIR101 as an adjunctive immunotherapy for hematopoietic stem cell transplant (HSCT) in adults with late-stage blood cancer.

The second Day 180 List of Issues was focused on one remaining major observation. In drafting the company's response, Kiadis has thoroughly analyzed this observation and have created multiple analyses of existing clinical data to address this observation, including analyses of various (pooled) ATIR and historical control data.

"We received the EMA's day 180 second list of outstanding issues in the fourth quarter of 2018, and have spent the past few months conducting additional analysis of existing data to support our response," said Arthur Lahr, CEO, of Kiadis Pharma. "With this submission complete, we aim to receive an opinion from Committee for Medicinal Products for Human Use (CHMP) in 2019. If the CHMP opinion is positive, it would enable us to receive a conditional marketing approval from the European Commission, followed by commercial use of ATIR101 in a first patient in a European country at the end of 2019."

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## About ATIR101

ATIR101 is an investigational allodepleted T-cell immunotherapy product candidate, which is designed to be given after a haploidentical (genetically half-matched) hematopoietic stem cell transplantation (HSCT).

Administered as an adjunctive immunotherapeutic on top of HSCT, ATIR101 provides a single dose donor lymphocyte infusion (DLI) with functional, mature immune cells from a haploidentical family member. The T-cells in ATIR101 will help fight infections and remaining tumor cells, until the immune system has fully re-grown from stem cells in the transplanted graft.

In ATIR101, T-cells that would cause GVHD are depleted from the donor lymphocytes, using our photodepletion technology. 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.

## **About Kiadis Pharma**

Founded in 1997, Kiadis Pharma, is a fully integrated biopharmaceutical company committed to developing innovative therapies for patients with late-stage blood cancers. With headquarters in

Amsterdam, the Netherlands, Kiadis Pharma is re-imagining medicine by leveraging the natural strengths of humanity and our collective immune system to source the best cells for life.

Kiadis Pharma is listed on the regulated market of Euronext Amsterdam and Euronext Brussels since July 2, 2015, under the symbol KDS. Learn more at <u>www.kiadis.com.</u>

### **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 forwardlooking 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.