



Kiadis Pharma changes strategy to focus solely on development of Natural Killer (NK) Cell therapeutics and terminates development of ATIR101

- ***Kiadis will focus all future investments on developing off-the-shelf and haplo donor NK-cell therapies for the treatment of solid and liquid tumors***
- ***Discontinues development of ATIR101, stopping phase 3 trial***
- ***Restructures organization; reducing workforce by approximately half***

Amsterdam, The Netherlands, 12 November 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 completed a strategic portfolio review and has decided to change its strategy and focus all resources and investments on the company’s NK-cell therapy platform and product candidates. The company will discontinue development of ATIR101 and stop its ongoing phase 3 trial.

Kiadis’ NK-cell program consists of off-the-shelf and haplo donor cell therapy products for the treatment of liquid and solid tumors. Kiadis’ proprietary off-the-shelf NK-cell platform is based on NK-cells from unique universal donors, expanded and activated *ex vivo* using our PM21 particle technology. The Kiadis off-the-shelf platform has the potential to make NK-cell therapy products rapidly and economically available for a broad patient population across a potentially wide range of indications.

The company’s pipeline includes:

- K-NK002: A phase 1/2 study will begin in 2020 evaluating K-NK002 as an adjunctive treatment to the current standard-of-care haploidentical hematopoietic stem cell transplantation (HSCT) with post-transplant cyclophosphamide (PTCy). Relapse remains an issue with the PTCy protocol. The phase 1/2 study was designed based on promising clinical proof-of-concept data in 25 patients that demonstrated a reduction of long-term relapse rates from 45% in a matched contemporaneous control of patients treated with PTCy, to 8% of patients treated with PTCy and K-NK002 (Blood 2017, ASCO 2018). The 63 patient phase 1/2 study will be conducted in collaboration with the Bone Marrow Transplant Clinical Trial Network (BMT-CTN), which consists of the premier transplant clinics in the United States.
- K-NK003: A phase 1/2A study will begin in 2020 evaluating K-NK003 as a treatment for patients with relapse and refractory acute myeloid leukemia. The trial is designed based on clinical proof-of-concept data that showed a 69% complete response rate (Haplo 2018).

- Pre-clinical programs: Kiadis has multiple preclinical programs evaluating its K-NK-cell therapies for the treatment of solid tumors.

Arthur Lahr, CEO of Kiadis Pharma commented, “We believe that our proprietary NK-cell therapy platform has broad potential as stand-alone or adjunctive treatments for patients with both liquid and solid tumors. Our off-the-shelf NK-cell platform is based on NK-cells from unique universal donors, expanded and activated with our PM21 particle technology, to make our NK-cell therapy products rapidly and economically available for patients across a potentially broad range of indications. The proof-of-concept trials for our NK pipeline programs, in which 38 patients have been treated, is very promising and was the basis for our acquisition of Cytosen Therapeutics, Inc. earlier this year. To confirm findings from these trials, we will start two Phase 1/2 clinical trials in 2020. We believe that investing in our NK platform and rapidly advancing development of our off-the-shelf and haplo donor derived NK-cell therapies in solid and liquid tumors will bring value to patients and our investors.”

Lahr continued, “As part of our strategic portfolio review, we reviewed progress of our phase 3 study, which was designed to show superiority of ATIR101 over the PTCy protocol. We identified that in the phase 3 a higher percentage of patients than expected dropped out of the study before receiving ATIR101. We subsequently collected additional recent external data, which show that outcomes with PTCy have better survival and lower severe GVHD than literature showed when we designed and started the phase 3 study. Based on these data, we no longer believe that the phase 3 ATIR study as currently designed with 250 patients can demonstrate superiority over PTCy and at a minimum would require a much larger trial. In the best interest of patients, we have therefore taken the decision to discontinue the ATIR101 study with immediate effect and are proceeding with close down activities.”

Restructuring

Kiadis is implementing a restructuring program to refocus the organization on its NK-cell therapy platform, which will result in a reduction of approximately half of its workforce, a reduction in external clinical trial costs associated with the phase 3 study, and a reduced company cash burn. The company ended the third quarter of 2019 with approximately €47 million of cash.

About Kiadis’ K-NK-Cell Therapies

Kiadis’ NK-cell programs consist of off-the-shelf and haplo donor cell therapy products for the treatment of liquid and solid tumors as adjunctive and stand-alone therapies.

Our NK-cell PM21 particle technology enables improved *ex vivo* expansion and activation of anti-cancer cytotoxic NK-cells supporting multiple high-dose infusions. Kiadis’ proprietary off-the-shelf NK-cell platform is based on NK-cells from unique universal donors. The Kiadis off-the-shelf K-NK platform can make NK-cell therapy product rapidly and economically available for a broad patient population across a potentially wide range of indications.

Administered as an adjunctive immunotherapeutic on top of HSCT, K-NK002 provides functional, mature and potent NK-cells from a haploidentical family member. In addition, Kiadis is developing K-NK003 for the treatment of relapse/refractory acute myeloid leukemia and has pre-clinical programs evaluating NK-cell therapy for the treatment of solid tumors.

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About Kiadis

Founded in 1997, Kiadis Pharma, is a fully integrated biopharmaceutical company committed to developing innovative cell-based therapies for patients with life-threatening diseases. With headquarters in Amsterdam, the Netherlands, and offices and activities in the US and across Europe, Kiadis Pharma is 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 www.kiadis.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 impact of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, regulation, 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.