Kiadis Pharma provides regulatory update on ATIR101

- ***Kiadis no longer expects EU conditional marketing authorization for ATIR101 in 2020***
- ***Kiadis plans to refile at the conclusion of the ongoing phase 3 trial***

Amsterdam, The Netherlands, 17 October 2019 – Kiadis Pharma N.V. ("Kiadis Pharma" or the "Company") (Euronext Amsterdam and Brussels: KDS), a clinical-stage biopharmaceutical company, today announced that it no longer expects to receive EU conditional marketing authorization for ATIR101 in 2020. The Company expects that European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) will issue a negative opinion and recommend against conditional marketing authorization at the next CHMP meeting in November 2019.

Arthur Lahr, CEO of Kiadis Pharma commented, "Today's news is very disappointing, especially for patients who could benefit from treatment with ATIR101. We filed a marketing authorization application (MAA) in 2017 with our phase 2 ATIR101 data and historical T-cell deplete haploidentical hematopoietic stem cell transplant (HSCT) control data based on input from EMA that these were considered adequate for review. Feedback from the EMA now indicates that the phase 2 data and historical T-cell deplete control data do not provide adequate support for a marketing authorization due to the evolution of the standard of care with the post-transplant cyclophosphamide (PTCy, aka Baltimore) protocol."

Kiadis is currently enrolling a global, 250 patient, randomized phase 3 trial, comparing patients treated with ATIR101 after a T-cell deplete HSCT to patients treated with a T-cell replete haploidentical HSCT based on the PTCy protocol. Completion of enrolment and interim readout of the phase 3 study are expected in 2021. If positive, the study will be the basis for filing of a biologics license application (BLA) with the US Food and Drug Administration (FDA) and a new MAA with the EMA.

Mr. Lahr continued, "The randomized phase 3 trial, if positive, should address EMA's concerns, as it compares ATIR101 to the current standard of care, the PTCy protocol. HSCT patients are in need of new treatment options and we will work diligently to advance our HSCT programs, while also pursuing cancer therapeutics with our NK-cell platform."

Scott Holmes, CFO of Kiadis Pharma added, "We do not believe that this setback significantly changes the long-term revenue potential for ATIR or the near-term cash needs of Kiadis. Revenue expectations in the initial years of European launch were minimal and would not have provided a positive operating margin. Importantly, we planned for and are enrolling the phase 3 study necessary for potential regulatory approval in the United States, and now the European Union."

About ATIR101 and KNK002
Kiadis has two cell-based therapeutics in development for patients with late-stage blood cancer undergoing a hematopoietic stem cell transplant: T-cell based ATIR101 and NK-cell based KNK002. Administered as adjunctive immunotherapeutics on top of HSCT, ATIR101 and KNK002 provide lymphocyte infusions with functional, mature and potent immune cells from a haploidentical family member. The T-cells in ATIR101 and NK-cells in KNK002 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. Our NK-cell nanoparticle processing technology enables improved *ex vivo* expansion and activation of NK-cells supporting multiple high-dose infusions with potent anti-cancer cytotoxicity.

In addition, Kiadis is developing NK-cell based therapies for the treatment of relapse/refractory AML 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
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