Kiadis announces U.S. FDA approval of the Abigail Wexner Research Institute at Nationwide Children's Hospital's IND for a COVID-19 clinical trial with off-the-shelf K-NK cells using Kiadis' proprietary platforms

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Amsterdam, The Netherlands, September 14, 2020 – Kiadis Pharma N.V. ("Kiadis" or the "Company") (Euronext Amsterdam and Brussels: KDS), a clinical-stage biopharmaceutical company developing innovative cell-based medicines for the treatment of life-threatening diseases, today announces a collaboration with the Abigail Wexner Research Institute (AWRI) at Nationwide Children's Hospital to develop Kiadis-NK cells (K-NK cells) as a post-exposure pre-emptive therapy for COVID-19. The U.S. Food and Drug Administration (FDA) approved AWRI's investigational new drug application (IND) for a study in an adult population with off-the-shelf natural killer (NK) cells produced with Kiadis' proprietary Universal Donor and PM21 technologies. Kiadis and AWRI are developing the plan for initiation of the clinical study.

Kiadis has exclusively licensed from AWRI intellectual property related to NK cells for treatment of microbial infections, including SARS-CoV-2. The Company has recently initiated the preclinical and clinical development of its K-NK-ID101 COVID-19 program and is expecting to receive US government funding for this program.

Arthur Lahr, CEO of Kiadis commented, "This is the second IND approved by the U.S. FDA for K-NK cells produced with our PM21 platform, and the second IND approved for K-NK cells based on our Universal Donor off-the-shelf platform. We are excited to study whether K-NK cells have the anti-viral properties, safety profile and manufacturing scalability to be widely deployed as an off-the-shelf global countermeasure against COVID-19 and future pandemic threats. This FDA approval marks rapid progress with our K-NK-ID101 COVID-19 program and demonstrates the potential expansion with our K-NK cells into infectious disease."

"The coronavirus pandemic has had a significant impact on our world, but has also created opportunities for innovation and forward thinking," says Dean Lee, MD, PhD, Director of the Cellular Therapy and Cancer Immunotherapy program at Nationwide Children's Hospital. "Data from patients with COVID-19 have demonstrated an important role for NK cells in this disease. Our previous collaborations with Kiadis in developing NK cells for cancer enabled us to design a novel Phase I/II clinical trial that meets FDA rigor in testing whether adoptive transfer of NK cells is safe and effective in mitigating progression of this virus in high-risk patients."

Dutch Translation/Nederlandse vertaling

Kiadis nv ('Kiadis') is een een Nederlands beursgenoteerd biotechbedrijf dat nieuwe geneesmiddelen ontwikkelt tegen ernstige ziekten. Het maakt daarbij gebruik van Natural Killer-cellen (NK-cellen), grote witte bloedlichamen die de eerste verdedigingslinie in het menselijk afweersysteem vormen tegen kankercellen en infecties.

De Amerikaanse Food and Drug Administration (FDA) keurde een aanvraag van Nationwide Children's Hospital (NCH) in Columbus, Ohio, goed voor een klinische studie in volwassenen met Kiadis K-NK cellen geproduceerd met Kiadis' *Universal Donor- en PM21 platform*. Kiadis en NCH bereiden momenteel de start van de studie voor.

Kiadis startte onlangs met de preklinische en klinische ontwikkeling van haar K-NK-ID101 programma voor de behandeling en preventie van COVID-19, en verwacht van de Amerikaanse overheid subsidie te ontvangen.

Arthur Lahr, CEO van Kiadis zegt:
"Dit is de tweede door de FDA goedgekeurde klinische studie met K-NK-cellen op basis van ons PM21-platform en ons Universele Donorplatform. K-NK-cellen beschikken over de juiste antivirale eigenschappen, veiligheidsprofiel en de productieschaalbaarheid om breed te kunnen worden ingezet tegen COVID-19 en toekomstige wereldwijde pandemieën. Deze FDA-goedkeuring is tekenend voor de snelle voortgang met ons K-NK-ID101 COVID-19-programma, en toont de potentie van onze K-NK-cellen voor de behandeling van infectieziekten."

Dean Lee, MD PhD, Directeur van het *Cellular Therapy and Cancer Immunotherapy Program* van het Nationwide Children's Hospital, zegt:
"De corona-pandemie heeft grote impact, maar biedt ook kansen op innovatie. Data van patiënten met COVID-19 heeft aangetoond dat NK-cellen een belangrijke rol spelen. De ontwikkeling van K-NK-cellen voor kanker hielp bij het opzetten van deze nieuwe door de FDA goedgekeurde fase I/II klinische studie naar de veiligheid en effectiviteit van adoptieve overdracht van K-NK-cellen voor het inperken van het corona virus bij hoog-risicopatiënten."

Dit persbericht vormt een vertaling van het gepubliceerde Engelstalige persbericht. Bij eventuele verschillen is de tekst van het Engelstalige persbericht altijd bepalend.

About NK-cells and K-NK-cells in COVID-19
The scientific rationale for studying the infusion of natural killer (NK) cells to control COVID-19 disease is supported by literature. The vast majority of COVID-19 patients have lymphocytopenia, or a shortage of lymphocytes – a type of white blood cell that helps protect the body from infection. NK cells are lymphocytes and COVID-19 disease severity is correlated with a reduction in the number of NK cells, exhaustion of NK cells and the lack of certain mature, potent NK-cell phenotypes. The power of NK cells to fight various other viral infections, such as CMV, BKV, HBV and HCV, has been well described, with a durable change in the NK-cell profile towards those more mature and potent phenotypes in recovered patients.

Kiadis research is aimed at studying the properties of Kiadis K-NK cells and their suitability to fight SARS-CoV-2 and to be developed as pre-exposure

prophylaxis and post-exposure pre-emptive therapy in high risk patients and healthcare workers. K-NK cells enhance multiple aspects of antiviral immunity. In immunocompromised transplant patients, K-NK cells have shown significant reduction of potentially lethal CMV reactivation and BKV infection. K-NK cells work synergistically with antibodies, immunoglobulins and vaccines.

K-NK cells are being studied regarding their anti-viral properties, safety profile and manufacturing scalability to potentially be widely deployed as an off-the-shelf global countermeasure against COVID-19 and future pandemic threats.

About Kiadis' K-NK-cell Based Medicines
Kiadis' NK-cell programs consist of off-the-shelf and haplo donor cell-based medicines for the treatment of liquid and solid tumors as adjunctive and stand-alone therapies. Kiadis is also researching the use of its' K-NK cell therapy platform for the treatment of infectious diseases, with the first potential application being the treatment of COVID-19.

The Company's 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 based product rapidly and economically available for a broad patient population across a potentially wide range of indications.

Kiadis is clinically developing K-NK003 for the treatment of relapse/refractory acute myeloid leukemia. The Company is also developing K-NK002, which is administered as an adjunctive immunotherapeutic on top of HSCT and provides functional, mature and potent NK-cells from a haploidentical family member. Furthermore, Kiadis is developing K-NK-ID101 for the treatment of Covid-19. In addition, the Company has pre-clinical programs evaluating NK-cell based medicines for the treatment of solid tumors and infectious diseases.

About Kiadis
Founded in 1997, Kiadis is building a fully integrated biopharmaceutical company committed to developing innovative cell-based medicines for patients with life-threatening diseases. With headquarters in Amsterdam, the Netherlands, and activities across the United States, Kiadis is reimagining medicine by leveraging the natural strengths of humanity and our collective immune system to source the best cells for life.

Kiadis 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.

Disclosures: Dr. Lee was a co-founder of CytoSen prior to its acquisition by Kiadis in 2019 and is currently chair of Kiadis' scientific advisory board (SAB). He holds stock in Kiadis, and has received financial compensation from Kiadis for consulting, for serving on the Company's SAB, and for intellectual property licensed to Kiadis through Nationwide Children's Hospital. Dr. Lee will receive milestone payment distributions related to the IP license.

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