Kiadis announces new data demonstrating FC21-NK cells were well tolerated and showed encouraging signs of antitumor and suspected antimicrobial activity in 13 patients with relapsed/refractory acute myeloid leukemia (R/R AML)

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- New data will be presented in an e-poster today at the Virtual Edition of the 46th EBMT Annual Meeting

Amsterdam, The Netherlands, August 29, 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 that new data supporting the Company's NK cell therapy is being presented at the 46 th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT). The poster presents data from 13 patients treated with relapsed/refractory acute myeloid leukemia (R/R AML) who received treatment with FC21 expanded NK-cells during a Phase I study conducted by Lucia Mariano da Rocha Silla, MD, PhD, at Hospital de Clínicas de Porto Alegre (HCPA) in Brazil. In this study, sponsored by the Brazilian Agencies for Research development, the adoptive transfer of haploidentical expanded NK cells to restore NK cell numbers and anti-leukemia function in patients with relapsed/refractory AML was investigated.

Abstract #A-1137-0005-00784: Phase I Study of Adoptive Transfer of Haploidentical Expanded NK Cells

Patients with relapsed, refractory, or CNS-positive AML respond poorly to chemotherapy. Naturally occurring NK cells have anti-leukemic activity but are deficient in numbers and function in AML patients and are ablated by high dose chemotherapy. The adoptive transfer of haploidentical expanded cells to restore NK cell number and anti-leukemic function in patients with relapsed/refractory AML was studied.

In this Phase I study, haploidentical donors were selected after HLA and KIR typing. NK cells were expanded on feeder cells and cryopreserved for infusion at the assigned dose level, then thawed and infused three times per week over 2 weeks, for a total of six doses, following fludarabine, cytarabine, and G-CSF (FLAG) treatment. Patients were treated in 3 dose cohorts of 10^6, $5x10^6$, and 10^7 NK cells/kg/infusion. Response was assessed at day 30.

In this study, 13 patients, ages 2 – 61 years, with primary refractory (n=5) or relapsed (n=8) AML were treated (one patient was treated twice). Patients had a median of five prior therapies, and nine had undergone prior stem cell transplantation. Four patients had disease in the central nervous system (CNS), including one patient with bone and nerve root disease and one with probable mycetoma. The FC21-NK-cell therapy was well tolerated with manageable toxicity. Complete response and overall response rates were 50% and 78.6%, respectively, including unexpected CNS responses that were associated with localized inflammation. Median overall survival and disease-free survival after treatment were 231 and 186 days, respectively. The data show that repeated infusions of cryopreserved FC21-NK cells are well-tolerated and demonstrate encouraging systemic and CNS responses in this heavily pretreated and fragile population of high-risk AML patients.

Dr. Silla commented, "In this highly refractory patient population, these data are very encouraging as the outcomes suggested potent activity of FC21-NK cells, particularly given that all 13 of these patients were R/R to prior FLAG therapy. Additionally, the positive impact on the four patients with microbial diseases associated with their AML was very promising and demonstrates the potential benefits of non-targeted NK-cell therapy in this patient population."

Arthur Lahr, chief executive officer of Kiadis, commented, "We are very pleased to see the encouraging outcomes from this completed study. This provides further support that FC21-NK cells used to treat R/R AML patients, complicated with CNS disease and serious infections, were well tolerated and can potentially serve as a treatment for these patients, especially older and frail AML patients who have few options available."

The e-poster titled "Phase I Study of Adoptive Transfer of Haploidentical Expanded NK Cells" can be found on the Kiadis website at https://www.kiadis.com/publications-posters/.

About Relapsed/Refractory Acute Myeloid Leukemia (R/R AML)

Acute myelogenous leukemia (AML) is the most common type of acute leukemia in adults and has the lowest survival rate of all leukemias. AML relapse affects nearly half of all leukemia patients who achieved remission after initial treatment and can continue to occur several months to several years after treatment with the majority of relapses occurring within two to three years of the initial treatment. Patients with relapsed or refractory leukemia have limited treatment options and poor survival rates.

The goal of treatment for acute myeloid leukemia (AML) is to put the leukemia into complete remission and to keep it that way. Unlike conventional chemotherapy options, which primarily target dividing cells, immunotherapeutic therapies aim at directing an immune response against tumor cells. Natural Killer (NK) cells are effector lymphocytes of the innate immune system capable of exerting anti-AML activity. The K-NK cell platform is a cell-based immunotherapy to treat patients with advanced blood cancer.

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Dutch Translation/Nederlandse vertaling

Kiadis nv ('Kiadis') is 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. Kiadis maakt bekend dat nieuwe studiedata met haar NK-celtherapie worden gepresenteerd op de 46e jaarlijkse bijeenkomst van de European Society for Blood and Marrow Transplantation (EBMT).

De zogeheten *poster* betreft data van behandeling van 13 patiënten met recidiverende/refractaire acute myeloïde leukemie (R/R AML), of terugkerende beenmergkanker, met FC21 geëxpandeerde NK-cellen tijdens een fase I-onderzoek uitgevoerd door Lucia Mariano da Rocha Silla, MD, PhD, in Hospital de Clínicas de Porto Alegre (HCPA) in Brazilië, gesponsord door de *Brazilian Agencies for Research Development*.

Abstract #A-1137-0005-00784: Fase I-studie adoptieve overdracht van haplo-identieke geëxpandeerde NK-cellen

Patiënten met recidiverende refractaire acute myeloïde leukemie reageren slecht op chemotherapie. Natuurlijk voorkomende NK-cellen van patiënten kunnen antileukemische werking hebben, maar worden gedood en verzwakt door de hoge doses chemotherapie die deze patiënten krijgen. De toediening van buiten de patiënt geëxpandeerde NK cellen als behandeling van leukemie werd in deze studie bestudeerd.

In deze fase I-studie werden haplo-identieke donoren geselecteerd na HLA- en KIR-typering. NK-cellen werden geëxpandeerd op voedercellen en ingevroren, vervolgens ontdooid en per infuus gedurende twee weken toegediend, na een voor-behandeling met fludarabine, cytarabine en G-CSF (FLAG). Patiënten werden behandeld in 3 groepen van 10^6, $5x10^6$ en 10^7 NK-cellen/kg per doses, en elke patiënt kreeg 5 of 6 doses. De respons werd beoordeeld op dag 30.

In de studie werden 13 patiënten in de leeftijd van 2-61 jaar met primaire refractaire (n=5) of recidiverende (n=8) AML behandeld (één patiënt werd tweemaal behandeld). Patiënten hadden gemiddeld vijf eerdere behandelingen gehad en negen hadden een eerdere stamceltransplantatie ondergaan. Vier patiënten hadden een ziekte in het centrale zenuwstelsel (CZS), waaronder één patiënt met bot- en zenuwwortelziekte en één met schimmelinfectie in de hersenen. De FC21-NK-celtherapie werd goed verdragen. De volledige respons en de algehele respons waren respectievelijk 50% en 78,6%, inclusief CZS-responsen. De mediane totale overleving was 231 dagen, ziektevrije overleving was 186 dagen. De gegevens tonen aan dat herhaalde infusies van ingevroren FC21-NK-cellen goed worden verdragen en bemoedigende systemische en CZS-reacties laten zien in deze zwaar voor-behandelde en kwetsbare populatie van hoog-risico AML-patiënten.

Dr. Rocha Silla, MD, PhD, van het Hospital de Clínicas de Porto Alegre (HCPA) in Brazilië, zegt:

"Voor een ernstig refractaire patiëntenpopulatie als deze zijn deze resultaten zeer bemoedigend. De resultaten wijzen op een krachtige werking van FC21-NK-cellen, vooral omdat alle 13 patiënten recidiverend/refractair waren na een eerdere FLAG-therapie. Bovendien zijn de positieve resultaten op bacteriële en schimmel infecties bij vier patiënten veelbelovend. De studie toont de mogelijke waarde van NK-celtherapie bij deze patiëntenpopulatie. "

Arthur Lahr, chief executive officer van Kiadis, vult aan:

"Dit zijn bemoedigende resultaten voor de werking van FC-21NK-cellen bij de behandeling van ernstig zieke patiënten met acute leukemie. Diverse patiënten hadden ernstige complicaties aan het centraal zenuwstelsel en ernstige infecties. De NK cellen lieten een krachtige respons zien, bij patiënten waar diverse eerdere behandelingen hadden gefaald. Deze NK cel therapie zal verder worden ontwikkeld voor deze vaak oudere en kwetsbare AML-patiënten waarvoor momenteel weinig behandelopties voorhanden zijn."

De e-poster met de titel "Phase I Study of Adoptive Transfer of Haploidentical Expanded NK Cells" is te vinden op de Kiadis-website op **https://www.kiadis.com/publications-posters/.**

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

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 and infectious diseases.

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.

Forward Looking Statements

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect Kiadis' or, as appropriate, Kiadis' officers' current expectations and projections about future events. By their nature, forward-looking statements involve a number of known and unknown risks, uncertainties and assumptions that could cause actual results, performance, achievements or events to differ materially from those expressed, anticipated 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, regulation, competition and technology, can cause actual events, performance, achievements or results to differ significantly from any anticipated or implied 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 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 projections, or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither Kiadis 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 anticipated or implied developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.