Kiadis Pharma announces FDA clearance of clinical study by The Ohio State University in R/R AML with off-the-shelf NK cells from universal donors

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Amsterdam, The Netherlands, February 26, 2020 – Kiadis Pharma N.V. ("Kiadis" or the "Company") (Euronext Amsterdam and Brussels: KDS), a clinical stage biopharmaceutical company, and The Ohio State University - Arthur G. James Cancer Hospital and Richard J. Solove Research Institute ("OSU" or "OSUCCC-James"), today announced the launch of a first-in-human clinical trial in patients with relapsed/refractory acute myeloid leukemia (R/R AML) with off-the-shelf Natural Killer ("NK") cells manufactured using Kiadis' FC21 mbIL21 feeder cells and proprietary universal donor platform. The trial is expected to provide further clinical proof-of-concept of Kiadis' K-NK003 product.

The investigator-sponsored trial will be conducted at OSUCCC – James, a National Cancer Institute (NCI)-designated comprehensive cancer center and freestanding cancer hospital located in Columbus, Ohio, in the United States. The OSUCCC – James team received Food and Drug Administration (FDA) approval for an investigational new drug application to begin this trial and expects to begin enrolling patients in March 2020. Kiadis will support the study through a collaborative research agreement with OSUCCC-James. Additionally, OSU and Kiadis plan to work together to initiate a company sponsored trial with off-the-shelf K-NK003 cells expanded with Kiadis' particle production platform (PM21) in the same patient population later this year.

The study entitled "A Phase I Clinical Trial Testing the Safety of IL-21-Expanded, Off-the-shelf, Third-party Natural Killer Cells for the Induction of Relapsed/Refractory Acute Myeloid Leukemia and Myelodysplastic Syndrome" will evaluate the NK cell product in up to 56 patients, ages 18 – 80 who have primary refractory AML, relapsed AML, or myelodysplastic syndromes (MDS). The goal of this study is to establish safety of the NK cell therapy for the induction of remission in patients with Relapsed/Refractory ("R/R") AML or MDS and to determine the optimal dosing and overall response rate. Patients enrolled in the study will receive six doses of NK cells of 1 x 10^7 cells/kg to 1 x 10^8 cells/kg after receiving reinduction chemotherapy.

"NK cells given outside the setting of transplantation have shown to induce remissions. Relapsed/refractory AML and MDS patients have a high chance of progression while waiting for manufacturing of expanded *directed-donor* NK cells, so having an easily accessible product, and one that does not require administration of cytokines, may be an attractive approach for these patients," stated Sumithira Vasu, MBBS, a hematologist scientist and Medical Director of the Cell Therapy Lab at OSUCCC - James who will serve as principal investigator of the clinical trial. Vasu is also an associate professor at The Ohio State University College of Medicine. "This trial uses a novel off-the-shelf, readily available product to treat what is traditionally a very sick and difficult-to-treat group of patients. I look forward to the collaboration with Kiadis to help accelerate development of this cell therapy."

"We are very pleased to be working with OSU and Dr. Vasu on the first clinical evaluation of our off-the-shelf universal donor K-NK-cell therapy in R/R AML as part of our K-NK003 cell therapy product program," says Andrew Sandler, MD, chief medical officer of Kiadis. "While this study will use our FC21 technology, we plan to leverage this study to initiate a company sponsored study at OSU and other sites with our particle production platform (PM21) in the same patient population later this year. Our proprietary PM21 platform is the only technology that produces NK-cell therapy without the use of feeder cell lines, which carry the risk of tumor cells and DNA in the final product."

The NK cell product will be manufactured in the OSU Cell Therapy Lab under the direction of Lynn O'Donnell, PhD, Director of Cell Therapy Engineering at OSUCCC - James Pelotonia Institute for Immuno-Oncology.

O'Donnell notes this off-the-shelf NK cell therapy is unique in several ways:

- It is derived from normal human donors who have undergone the full FDA-mandated screening process and are demonstrating excellent NK cell expansion using the Kiadis FC21 technology.
- The OSUCCC – James team is able to bank the cells ahead of patient enrollment. "Because of this, we do not need to wait for QC/QA release or 'matching' the donor to the recipient, saving weeks of critical time for patients with aggressive disease, " says O'Donnell, who also serves as an associate professor at The Ohio State University College of Medicine.
- The NK cells are not genetically engineered like CAR-T cells, CAR-NK cells, or other allogeneic NK cell products, which O'Donnell notes eliminates the need for long-term follow up of patients, and reduces the overall regulatory burden.
- NK cells are not derived from induced pluripotent stem cells or an irradiated tumor cell line, eliminating another source of risk for the patients long-term.

Vasu and O'Donnell have no potential financial conflicts of interest related to Kiadis or this study to disclose.

About Kiadis

Founded in 1997, Kiadis Pharma is building a fully integrated biopharmaceutical company committed to developing innovative therapies for patients with life-threatening diseases. With headquarters in Amsterdam, the Netherlands, and offices and activities across the United States, Kiadis Pharma is reimagining 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 kiadis.com.

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