Kiadis Pharma receives FDA Regenerative Medicine Advanced Therapy (RMAT) designation for ATIR101™

Amsterdam-Duivendrecht, The Netherlands, September 20, 2017 – Kiadis Pharma N.V. **("Kiadis Pharma" or the "Company") (Euronext Amsterdam and Brussels: KDS)**, a clinical stage biopharmaceutical company developing innovative products to make bone marrow transplantations safer and more effective for patients suffering from blood cancers and inherited blood disorders, today announces that the US Food and Drug Administration (FDA) has granted ATIR101™, Kiadis Pharma's lead investigational product for blood cancers, the Regenerative Medicine Advanced Therapy (RMAT) designation.

Arthur Lahr, CEO of Kiadis Pharma, commented: *"To receive the RMAT designation from the FDA is an important milestone for Kiadis Pharma and a recognition by the FDA of the significant potential for ATIR101™ to help patients receive safer and more effective bone marrow transplantations. RMAT is analogous to the Breakthrough Therapy designation, and a clear validation of ATIR101™ towards doctors and investors. We are now going to work even closer with the FDA to agree a path to make this cell therapy treatment available for patients in the US as soon as possible. In Europe ATIR101™ was filed for registration in April 2017 and we continue to prepare the Company for the potential European launch in 2019."*

The RMAT pathway is analogous to the Breakthrough Therapy designation designed for traditional drug candidates and medical devices, and was specifically created by the US Congress in 2016 to get important new cell therapy and advanced medicinal products to the patient earlier. Just like the Breakthrough designation, it allows companies developing regenerative medicine therapies to interact with the FDA more frequently in the clinical testing process, and RMAT-designated products may be eligible for priority review and accelerated approval.

A regenerative medicine is eligible for the RMAT designation if it is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition.
For more information on RMAT designation, visit the FDA website:
https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm537670.htm).

FDA has already requested an additional meeting with Kiadis Pharma and will now work closely with the Company to provide guidance on the subsequent development of ATIR101™ for improved overall survival and reduced transplant related mortality for patients receiving a haploidentical hematopoietic stem cell transplantation (HSCT).

About Kiadis Pharma
Kiadis Pharma is focused on cell-based immunotherapy products, as an adjunctive to a haploidentical hematopoietic stem cell transplantation (HSCT), for the treatment of blood cancers and inherited blood disorders. The Company's product candidates have the potential to make allogeneic HSCT safer and more effective for patients.

Based on the positive results from the single dose Phase II trial with lead product ATIR101™ in patients with blood cancer, the Company submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in April 2017, for approval of ATIR101™ across the European Union as an adjunctive treatment in HSCT for malignant disease. In addition, Kiadis Pharma has received regulatory approval in various countries to start dosing patients in a Phase III trial with ATIR101™ that will be performed across Europe and North America. ATIR101™ has been granted Orphan Drug Designations both in the US and Europe.

The Company's second product candidate, ATIR201™, will address beta thalassemia, an inherited blood disorder.

Kiadis Pharma was granted an Advanced Therapy Medicinal Product (ATMP) certificate for manufacturing quality and non-clinical data by the EMA.

The Company's shares are listed on Euronext Amsterdam and Euronext Brussels.
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