



Kiadis Pharma provides update on the Marketing Authorization Application process for ATIR101™ in Europe

Amsterdam-Duivendrecht, The Netherlands, September 27, 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 Company has received and reviewed the Day 120 List of Questions (“LoQs”) for its lead product ATIR101™ from the European Medicines Agency's (“EMA”) Committee for Advanced Therapies (“CAT”). Following review of the LoQs, Kiadis Pharma expects that it will be able to address all questions within the six months response time that has been agreed with EMA.

Kiadis submitted the marketing authorization application (“MAA”) for ATIR101™ to the EMA in April 2017 and CAT issued the Day 120 LoQs in September 2017. Under the EMA review process, the CAT review of the MAA will resume with Day 121 upon submission of Kiadis Pharma’s response.

Arthur Lahr, CEO of Kiadis Pharma, commented: *“We expect to adequately address EMA’s questions within the coming six months. Kiadis Pharma is on track to potentially obtain (conditional) EMA approval for ATIR101™ in the second half of 2018, which would allow for a European launch in 2019.”*

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. In September 2017 the US Food and Drug Administration granted ATIR101™ the Regenerative Medicine Advanced Therapy designation.

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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