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Kiadis Pharma provides regulatory and clinical update on ATIR101

Potential CHMP opinion moved from Q4 2018 into H1 2019
Guidance for initial EU commercial launch in H2 2019 unchanged
FDA meeting held under RMAT status
Phase 3 study on track with over 20 open sites expected by end 2018, of which several in US

Amsterdam, The Netherlands, October 12, 2018 - Kiadis Pharma N.V. ("Kiadis Pharma" or the "Company") (Euronext Amsterdam and Brussels: KDS), a clinical-stage biopharmaceutical company, today announces a regulatory and clinical update for ATIR101.

Europe EMA

Following recent meetings of the Committee for Advanced Therapies (CAT) and the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), Kiadis Pharma received a Day 180 second List of Outstanding Issues relating to its marketing authorization application (MAA) for ATIR101. Kiadis Pharma has completed its evaluation of these remaining Day 180 questions. Addressing the questions will require additional analyses of existing clinical data. As expected, no new experimental or new clinical data needs to be generated. EMA has accepted the Company's request for the time needed to respond to the remaining questions. As a result, the timing of the expected CHMP opinion has moved from the fourth quarter of 2018 into the first half of 2019. Following potential EU approval, which typically follows a positive CHMP Opinion within 67 days, Kiadis Pharma intends to commercially launch ATIR101 in a first EU member state in the second half of 2019, which is unchanged versus previous guidance.

US FDA

In 2017, the US Food and Drug Administration (FDA) granted ATIR101 the Regenerative Medicine Advanced Therapy (RMAT) designation. Similar to a Breakthrough Therapy designation, RMAT status allows companies developing regenerative medicine therapies to interact with the FDA more frequently, and RMAT-designated products may be eligible for priority review and accelerated approval. As part of its RMAT status, Kiadis Pharma is benefitting from productive interactions with the US FDA, including a recent meeting.

Phase 3 clinical trial

The Company is on track with the ongoing Phase 3 clinical study to enroll 250 patients at leading transplant centers globally. The Company has now enrolled 22 patients and has 14 sites open in 7 countries. Kiadis Pharma expects to have over 20 sites open by the end of 2018, including several US sites. An interim analysis of the Phase 3 study is expected in the second half of 2020.

Arthur Lahr, CEO of Kiadis Pharma, commented: "*We are pleased with our continued clinical and regulatory progress and remain on track for the initial commercial launch of*

ATIR101 in a first EU country in the second half of 2019. We are confident that we can address the remaining questions from EMA, allowing for a CHMP opinion in the first half of 2019. The FDA granting the RMAT status is a clear validation of the importance of ATIR101 and has resulted in productive interactions with the US FDA. We are very pleased with progress made in our Phase 3 clinical trial to date. We are again a step closer to bringing ATIR101 to patients."

For more information, please contact:

Kiadis Pharma:
Karl Hård, Head of IR & Communications
Tel. +31 611 096 298
k.hard@kiadis.com

Optimum Strategic Communications:
Mary Clark, Supriya Mathur, Hollie Vile
Tel: +44 203 714 1787
David Brilleslijper (Amsterdam)
Tel: +31 610 942 514
kiadis@optimumcomms.com

About Kiadis Pharma
Kiadis Pharma is developing its lead product candidate, ATIR101, for use in conjunction with haploidentical (genetically half-matched) hematopoietic stem-cell transplantations (HSCT) for adult blood cancers to address key limitations of haploidentical HSCT, without prophylactic immunosuppression and its associated morbidity and mortality. Based on the positive results from the single dose Phase 2 CR-AIR-007 study, the Company submitted a marketing authorization application to the European Medicines Agency in April 2017 for approval of ATIR101 as an adjunctive treatment in haploidentical HSCT for high risk adult hematological malignancies. If the product is conditionally approved, Kiadis Pharma intends to launch ATIR101 through its own commercial organization in a first EU member state in the second half of 2019.

In December 2017, Kiadis Pharma commenced an international, multicenter, randomized and controlled Phase 3 clinical trial of ATIR101 against the Post-Transplant Cyclophosphamide, (PTCy) protocol, the main protocol used to perform a haploidentical HSCT. The trial will be performed in 250 patients with acute leukemia and myelodysplastic syndrome at approximately 50 sites in the United States, Canada, Europe and certain additional countries. ATIR101 received regenerative medicine advanced therapy (RMAT) designation from the FDA in September 2017, which provides benefits that are materially equivalent to a Breakthrough Therapy designation from the FDA. In addition, ATIR101 has been granted multiple orphan drug designations both in the European Union and the United States.

The Company's shares are listed on Euronext Amsterdam and Brussels under the ticker KDS.

Forward Looking Statements
Certain statements, beliefs and opinions in this press release are forward-looking, which reflect Kiadis Pharma's or, as appropriate, Kiadis Pharma's directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed 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, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated 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 Pharma expressly disclaims any obligation or undertaking to release any update or revisions to any forward-

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