



Kiadis Pharma announces initiation of a repeat-dosing Phase II clinical trial with ATIR101™

Amsterdam, The Netherlands, September 30, 2015 – Kiadis Pharma N.V. (“Kiadis Pharma” or “Company”) (Euronext Amsterdam and Brussels: KDS), a clinical stage biopharmaceutical company developing innovative T-cell immunotherapy treatments for blood cancers and inherited blood disorders, today announces that it has obtained regulatory approvals from the national authorities both in Canada and in Belgium to start a further Phase II clinical trial with its lead product ATIR101™. In this new trial the safety and efficacy of using a second dose of ATIR101™ will be studied (NCT02500550 / EudraCT 2015-002821-20).

ATIR101™ is a cell-based product designed to enable stem cell transplantations from partially matched (haploidentical) family donors for blood cancer patients who do not have a matching stem cell donor available. Previously announced results obtained in prior and ongoing clinical studies confirm the safety and efficacy of a single dose of ATIR101™ at 2×10^6 cells/kg, with no grade III-IV (life-threatening) acute Graft versus Host Disease (GvHD) occurring, despite the fact that no prophylactic immune suppressants were used. Furthermore, only limited severe infections and relapses were reported in those studies. The aim of the new Phase II trial is to test whether the administration of a second dose of ATIR101™ to a stem cell transplantation at a later point during treatment could further improve the transplantation outcome.

The study will commence in Canada and Belgium and the Company plans to expand the study to the USA and other European countries pending regulatory approvals. A total of 15 leukaemia patients with acute myeloid leukaemia (AML), acute lymphoblastic leukaemia (ALL) or myelodysplastic syndrome (MDS) will be enrolled. Kiadis Pharma expects to enroll the first patient into this study in Q4 2015.

Manfred Rüdiger, PhD, Chief Executive Officer of Kiadis Pharma, commented: *“We are excited to initiate another Phase II study with ATIR101™ on track with plans communicated at the time of our IPO. We have already demonstrated the potential of ATIR101™ to better protect patients against transplant related mortality and provide anti-leukaemia reactivity. The fully functional T-cells in ATIR101™, collected from a partially mismatched, haploidentical family-donor, are able to fight infections and residual tumour cells without eliciting acute grade III/IV GvHD in any patient as a result of Kiadis Pharma’s technology. In this next Phase II study we want to explore whether this effect can be even further maximized by administering a second dose of ATIR101™.”*

About ATIR™

During an allogeneic hematopoietic stem cell transplantation (HSCT) treatment, the bone marrow, harbouring the diseased cells, is completely destroyed and subsequently replaced by stem cells from a healthy donor. After an HSCT treatment it usually takes at least six to twelve months to recover to near-normal blood cell levels and immune cell functions in a

patient that has received a transplant. During this period, the patient is highly susceptible and vulnerable to infections caused by bacteria, viruses and fungi. Immune cells in ATIR™ (Allodepleted T-cell Immunotherapy) will help fight these opportunistic infections and bridge the time until the immune system has fully re-grown from stem cells in the transplanted graft.

In ATIR™, T-cells that cause Graft-versus-Host-Disease (GVHD) are eliminated from the donor lymphocytes, which minimises the risk of GVHD and any related morbidity and mortality. At the same time, ATIR™ contains potential cancer killing T-cells from the donor that could eliminate residual cancer cells and avoid the return of the disease. ATIR™ allows the use of haploidentical grafts that are almost entirely depleted of T-cells, which eliminates the need for immunosuppressive drugs. ATIR™ subsequently provides the patient with immune cells that do not cause GVHD. As a result, ATIR™ solves the problem of not finding a matched donor in time and has the potential to make curative HSCT a viable option to many more patients.

The Company estimates that approximately 35% of patients who are eligible for, and who are in urgent need of, HSCT will not find a matching donor in time. A partially matched (haploidentical) family donor, however, will be available to over 95% of patients. The use of haploidentical donor grafts without ATIR™ is only feasible in conjunction with severe immunosuppression which renders the patient highly vulnerable to infections with severe clinical complications, resulting potentially in death.

About Kiadis Pharma

Kiadis Pharma is a clinical stage biopharmaceutical company focused on research, development and future commercialisation of cell-based immunotherapy products for the treatment of blood cancers and inherited blood disorders. The Company believes that its innovative products have the potential to address the current risks and limitations connected with allogeneic hematopoietic stem cell transplantation (HSCT). Although currently not a viable option for many patients, HSCT is generally regarded as the most effective curative approach to blood cancers and certain inherited blood disorders. The Company expects that HSCT could become a first-choice treatment for blood cancers and inherited blood disorders once current risks and limitations are addressed, thereby meeting a significant unmet medical need with its products.

Currently, ATIR101™ is being tested using a single dose regimen in an open-label Phase II trial in patients with blood cancer who have not found a matching donor and where a partially matched (haploidentical) family member is used as donor for HSCT. Kiadis Pharma recently announced full enrolment of this trial.

Kiadis Pharma is based in Amsterdam, the Netherlands and its shares are listed on Euronext Amsterdam and Euronext Brussels. Further information can be found at: www.kiadis.com

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