

AMSTERDAM, The Netherlands, September 11, 2013 /PRNewswire/ --

~ 67% survival demonstrated after 5 years and no transplant related mortalities ~

Manfred Ruediger, CEO of Kiadis Pharma, gives more information on ATIR™ and the five-year follow-up data in a video available on <http://www.kiadis.com>

Kiadis Pharma B.V., a clinical stage biopharmaceutical company developing treatments for blood cancers, announced today that the five-year follow-up of patients with high-risk malignancies from its Phase I/II clinical study confirms long-term safety and efficacy of ATIR™ over a broad dose range. ATIR™ is a cell-based product designed to enable stem cell transplantations from partially mismatched (haploidentical) family donors for patients who do not have a standard of care stem cell donor available. The results demonstrate proof of concept and show that ATIR™ infusion after a T-cell depleted haploidentical hematopoietic stem cell transplantation (HSCT) provides immune protection shortly after the transplantation and improves long-term outcome in high-risk patients with very poor prognosis.

Not only does the study confirm that ATIR™ provides an effective treatment for patients for whom a standard of care stem cell donor is not available, the long term survival even seems to compare favorably to patients who do have a standard of care matched unrelated donor available. The overall survival of patients with high-risk malignancies in the Phase I/II study who received an efficacious dose of ATIR™ was 78% and 67% after one and five years, respectively. Data from the Center for International Blood & Marrow Transplant Research (CIMBTR) show that the one (and five) year survival of patients with acute myeloid leukemia

(AML) who do have a standard of care matched unrelated donor available, varies from 65% (and 35%) in low-risk patients to 45% (and 20%) in high-risk patients, respectively.

In this Phase I/II study, 19 high-risk leukemia patients were treated with escalating doses of ATIR™ after a haploidentical HSCT. The five-year follow-up data show no transplant related mortality in the nine patients who received an efficacious dose of ATIR™. In addition, no Grade III-IV (life-threatening) acute Graft versus Host Disease (GvHD) was observed at any dose, which again compares favorably to standard of care matched unrelated donor transplantations, where (according to data from the CIBMTR) incidence of life-threatening GvHD is 30%. The strong five-year survival data also suggest that immune cells responsible for the Graft versus Leukemia effect are retained in ATIR™.

The results of the study allowed selecting the optimal ATIR™ dose for further development. Data from this five-year study will be published in due course in a peer-reviewed medical journal.

An international multi-center Phase II study including patients with AML, acute lymphoblastic leukemia (ALL) and myelodysplastic syndrome (MDS), to confirm and extend the data from the Phase I/II study, is now ongoing with topline results of the first phase expected in H1 2014.

Manfred Ruediger, PhD, Chief Executive Officer of Kiadis Pharma, commented: "The results from this study, which spans five years, show that ATIR™ might change the way in which patients with hematological malignancies will be treated. These data show that ATIR™ not only prevents significant infections without eliciting life-threatening GvHD, but also strongly improves survival rates in patients with high-risk malignancies and very poor prognosis. Our currently ongoing international Phase II clinical study is designed to confirm and extend these data to expedite moving ATIR™ towards regulatory approval."

Dr. Denis-Claude Roy, Professor of Medicine at the University of Montreal and principal investigator for the study

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added:

"We are very excited about the long-term effects of ATIR™. In demonstrating very strong efficacy in minimizing post-transplantation risks and improving overall survival, these long-term data represent a potential major advancement in providing patients for whom a suitable matched donor is not available, with the opportunity to receive an HSCT from a mismatched

family member with ATIR™ added as an adjunctive treatment."

About ATIR™

ATIR™ is a cell-based medicinal product enabling stem cell transplantations using partially mismatched (haploidentical) family members as donors for patients suffering from blood cancer who do not have a standard of care stem cell donor available. An HSCT is the only potentially curative treatment for many patients but a matching donor is available for only half of the patients in need. ATIR™ thus has the potential to address this unmet need and to make the HSCT available for all patients worldwide.

Those T-cells in a haploidentical graft which would cause life-threatening GvHD are selectively eliminated using proprietary technology to produce ATIR™. ATIR™ is administered as an adjunctive treatment after a haploidentical HSCT facilitating early immune reconstitution without causing life-threatening (acute) GvHD.

ATIR™ is currently in Phase II clinical development and has been granted Orphan Drug Designation both in the EU and the USA. Together, both regions represent a combined primary market potential of more than EUR 1 billion per year.

About Kiadis Pharma

Kiadis Pharma B.V. is a private, clinical stage biopharmaceutical company focused on the development of innovative and potentially life-saving therapies for patients with late stage blood cancers and related disorders, an area of significant unmet medical need.

Kiadis Pharma's lead product is ATIR™, a cell-based product designed to enable stem cell transplantations from partially mismatched (haploidentical) family donors. ATIR™ is currently being studied in an international Phase II study. Kiadis Pharma recently obtained a GMP manufacturing license and GMP certificate for its Quality Control laboratory.

Kiadis Pharma Completes Five-year Follow-up of its Phase I/II Clinical Study with Blood Cancer Product A

Written by Australian Business

Kiadis Pharma is supported by a strong group of leading international investors including LSP, Alta Partners, DFJ Esprit, Quest for Growth, MedSciences Capital and NOM. Kiadis Pharma is based in Amsterdam, The Netherlands. Further information can be found at: <http://www.kiadis.com>

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