

Theralux™ ATIR may be Feasible Strategy for Mismatched Stem Cell Transplantation

Clinical Data Presented at Annual American Society of Hematology Meeting

Orlando, December 12, 2006 - Kiadis Pharma B.V. (formerly Celmed BioSciences Inc.) has announced Phase I data suggesting that its investigational Theralux™-ATIR (Add-Back of T Cell for Immune Reconstitution) technology reduced the risk of acute graft-versus-host disease among blood cancer patients who received donor lymphocyte infusions (DLI) following mismatched stem cell transplantation. Data were presented during the 48th Annual Meeting and Exposition of the American Society of Hematology (ASH).

DLI can help blood cancer patients achieve sustained remission after stem cell transplantation by restoring their immune system, which helps protect them against both infection and cancer relapse. However, donor cells known as "activated alloreactive T cells" can attack the tissues and organs of the patient (host), leading to a serious condition called acute graft-versus-host disease (GvHD). Theralux™-ATIR is designed to remove these harmful T cells from the donor graft while leaving T cells that help fight infection and cancer.

In an oral presentation, Denis-Claude Roy, M.D., Oncologist/Hematologist from the Stem Cell Transplantation Unit at the Maisonneuve-Rosemont Hospital in Montreal, Quebec, reported data on nine high-risk blood cancer patients who received stem cells transplanted from a "mismatched" donor (haploidentical transplantation) followed by a DLI in which activated alloreactive T cells were selectively removed with Theralux™-ATIR. No patient developed acute GvHD. Only one patient had a recurrence of his leukemia. Infectious complications occurring early post-transplant responded to treatment, potentially representing a sign of early immune reconstitution. Four patients are relapse-free survivors with a median follow-up of 10 months post transplantation.

"These results suggest that post-transplant infusion of Theralux™-ATIR treated cells is a feasible strategy that does not induce acute GvHD and may accelerate T cell reconstitution necessary to fight infections in these patients" said Dr. Roy. "In addition, Theralux™-ATIR may represent an option for patients at higher risk for GvHD due to higher age as the mean age at the time of transplantation was 55 years (range 21-58)".

In this dose-escalation study, to date, 9 patients with haploidentical stem cell donors received DLI add-back of up to 3.2×10^8 T cells per kilogram. The endpoints of the study are safety and efficacy: incidence and severity of acute GvHD and infections. Theralux™-ATIR, is based on the proprietary Theralux™ technology platform and designed to selectively eliminate activated alloreactive T cells responsible for acute GvHD, while sparing the T cell repertoire needed for immune reconstitution. If successful, this product could allow patients to undergo blood stem cell transplantation even if they cannot find matched donors. Additionally, this therapy could make matched blood stem cell transplantation much safer and would require

less immune suppression. The success of this approach would solve a long-standing problem and represent a shift in the way blood cancers are treated.

"The promise of Theralux™-ATIR was critical in the merger of Celmed BioSciences of Montreal and Kiadis", said Manja Bouman, CEO, Kiadis Pharma. "The data from this trial are very encouraging particularly when considering the age of the patients, the severity of the haematological malignancy and the available alternatives for patients without a matched donor."

Kiadis Pharma (formerly Celmed BioSciences) presented data from three different research programs, including the Phase I trial discussed above, at this year's ASH Meeting. Full titles are listed below:

Denis Claude Roy *et al.* "Phase I Clinical Study of Donor Lymphocyte Infusion Depleted of Alloreactive T Cells After Haplotype Mismatched Myeloablative Stem Cell Transplantation to Limit Infections and Malignant Relapse Without Causing Graft-Versus-Host Disease"

Stephan Mielke *et al.* "High Efficiency Clinical Scale Selective Depletion of Alloreacting T Cells Using Expanded T Lymphocytes as Antigen-Presenting Cells and a TH9402-Based Photodepletion Technique in HLA-Mismatched and Matched Donor-Recipient Pair"

NgocDiep Le *et al.* "Prevention of Graft Versus Host Disease by Selective Depletion of Alloreactive T Cells"

About Kiadis Pharma B.V.

Kiadis Pharma is fully dedicated to in-house pharmaceutical product development with extensive experience in oncology and full ownership of its products under development. The company has developed a number of small molecule drugs in various stages of clinical development from its proprietary technology platforms Theralux™, BioSelact™ and ECTA. Kiadis Pharma is headquartered in the Netherlands with facilities in Groningen, the Netherlands and Montreal, Canada.

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