

Paul-Ehrlich-Institut
Att. Dr. H. Krafft
Paul-Ehrlich-strasse 51-59
63225 Langen
Germany

Your reference
Vorlage 2870/01

Our reference
CR-BD-001-end

Dealt with by
Inge van Elburg

Direct line
+31 (0) 203140282

Place
Amsterdam-Zuidoost

Date
11 June 2018

e-mail
regulatory.affairs@kiadis.com

Subject: Declaration end of Clinical Trial CR-BD-001

EudraCT number: 2016-002959-17

Study number: CR-BD-001

Study title: An exploratory, open-label study to evaluate the safety and feasibility of ATIR201, a T-lymphocyte enriched leukocyte preparation depleted ex vivo of host alloreactive T-cells (using photodynamic treatment), as adjuvant treatment to a T-cell depleted haploidentical hematopoietic stem cell transplantation in patients with beta-thalassemia major

Dear Dr Krafft,

The company has taken the decision not to continue with the development of ATIR201 for thalassemia at this time due to a change of priorities. As a consequence, clinical trial CR-BD-001 is terminated early.

For this trial a "Genehmigung" was issued by the PEI on 30 March 2017. The company has chosen to notify the Competent Authorities using the "Declaration of the End of Trial Form".

Please note that no patients have been enrolled into this trial. As no data have been or will be gathered, the company does not intend to submit a Clinical Trial Summary Report.

If we do not receive any further questions or request for further clarification and/or documentation we shall assume that the matter is closed.

Thanking you in advance for your co-operation in this matter.

Kind regards,



Inge van Elburg
Regulatory Affairs

Enclosed: Declaration of the End of Trial Form