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06 November 2019

Dr. M. Schüssler-Lenz, CAT Chair
Dr. H. Enzmann, CHMP Chair
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Luxceptar (ATIR101), viable T-cells, dispersion for infusion - Procedure Number: EMEA/H/C/002397

Dear Dr. Schüssler-Lenz, Dear Dr. Enzmann,

Kiadis Pharma Netherlands B.V. (Kiadis Pharma) would like to inform you of the decision to withdraw the application for Marketing Authorisation of Luxceptar (ATIR101), viable T-cells, dispersion for infusion, which was intended to be used as an adjunctive treatment in haematopoietic stem cell transplantation (HSCT) for a malignant disease.

This withdrawal is based on the following reason:

- The CAT and the CHMP considers that the data provided are not sufficiently mature to conclude on the benefit-risk balance.

The Company confirms there is no impact for patients in ongoing clinical trials with ATIR101.

Kiadis Pharma remains fully committed to developing adjunctive treatments to HSCT for haematological malignancies.

Kiadis Pharma reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

Kiadis Pharma would like to sincerely thank the CAT (Co-)Rapporteurs, the CHMP Co-Coordinators, EMA and the scientific committees involved for their time dedicated to reviewing this application and the valuable support and helpful guidance provided during the review process.

Kiadis Pharma agrees for this letter to be published on the EMA website.

Yours sincerely