Better Health, Brighter Future

23 February 2024

Dr. Harald Enzmann
European Medicines Agency (EMA)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Adcetris (brentuximab vedotin) - EMEA/H/C/002455/II/0109 - Withdrawal of the application for a new indication

Dear Dr. Enzmann,

We would like to inform you that, Takeda Pharma A/S has taken the decision to withdraw the application to add a new indication for Adcetris in combination with cyclophosphamide, doxorubicin and prednisone for adult patients with previously untreated CD30+ Peripheral T-cell Lymphoma not otherwise specified (PTCL-NOS).

This withdrawal is based on interactions with the CHMP indicating that the data provided thus far would not be sufficient to support the proposed indication.

This withdrawal does not have any impact on ongoing clinical trials with Adcetris.

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

Takeda would like to sincerely thank the (Co-)Rapporteurs and the EMA for their time dedicated to reviewing this application and the helpful guidance provided during the review process.

We agree for this letter to be published on the EMA website.

Yours faithfully,
Takeda Pharmaceuticals International AG

Takeda Pharmaceuticals International AG
Thurgauerstrasse 130, CH-8152 Glattpark-Opfikon (Zürich), Switzerland | T +41 (0)44 55 51000 | F +41 (0)44 55 51001 | www.takeda.com
Company No. CHE-113.444.401