Bristol Myers Squibb™

[redacted]
Global Regulatory Science Europe
Research and Development
Route de Perreux 1, 2017 Boudry, Switzerland
[redacted]

Dr Harald Enzmann
CHMP Chairman
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

2024-02-19

Subject:
Withdrawal of ORENCIA (abatacept) type II variation EMEA/H/C/000701/II/0152 - EU/1/07/389/001-014

Dear Dr Enzmann,

I would like to inform you that, at this point of time, Bristol-Myers Squibb Pharma EEIG (BMS) has taken the decision to withdraw the application to add a new indication for ORENCIA (abatacept) for the prophylaxis of acute Graft versus Host Disease (aGvHD).

This withdrawal is based on the CHMP considerations that, despite the promising data shown for abatacept in the target indication, uncertainties in the context of the claimed signals of efficacy translating into clinically relevant treatment benefit, do not allow the Committee to conclude on a positive benefit risk balance at the present time.

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

We remain fully committed to the development of abatacept in aGvHD and reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

BMS would like to sincerely thanks the (Co-)Rapporteurs, EMA, PRAC and the CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

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

[redacted]