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janssen
PHARMACEUTICAL COMPANIES
OF Johnson-Johnson

02/07/2012

Dr Tomas Salmonson
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of VELCADE Type II variation to add a new indication for the treatment of patients with relapsed follicular non-Hodgkin lymphoma (EMEA/H/C/539/II/0055)

Dear Dr Salmonson,

I would like to inform you that, at this time, Janssen-Cilag International NV has decided to withdraw the Type II variation application for VELCADE in combination with rituximab for the treatment of adult patients with relapsed follicular non-Hodgkin lymphoma whose time since last antilymphoma therapy was greater than one year. This withdrawal is based upon the CHMP opinion that the data provided does not support a positive benefit/risk balance.

This decision will not affect patients enrolled in any ongoing Janssen Research & Development-sponsored VELCADE studies.

Clinical development of VELCADE is ongoing; therefore, Janssen-Cilag International NV reserves the right to submit future applications in this or other therapeutic indication(s). In addition, Janssen-Cilag International NV acknowledges that this letter will be published on the EMA website.

Yours sincerely,
For and On behalf of Janssen-Cilag International N.V.

[redacted]