MERCK SHARP & DOHME

To: Dr Abadie
CHMP Chairman
European Medicines Agency
7 Westferry Circus
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London
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United Kingdom

Cc: Dr Hector Boix-Perales
EMEA Project Leader

Dr. Ian Hudson (Rapporteur)
MHRA

Dr. Jens Ersbøll (Co-Rapporteur)
DMA

Brussels, 13 February 2009

Subject: Withdrawal of Marketing Authorisation Application for Vorinostat MSD, 100 mg, hard capsules (EMEA/H/C/947)

Dear Dr Abadie,

I would like to inform you that, at this point of time, Merck Sharp & Dohme Ltd. (the "Company") has taken the decision to withdraw the application for Marketing Authorisation for Vorinostat MSD, 100 mg, hard capsules, which was intended to be used for *the treatment of patients with advanced stage cutaneous T-cell lymphoma (CTCL) who have progressive, persistent, or recurrent disease who have failed at least two prior systemic therapies.*

This withdrawal is based on the Company's understanding of recent interactions with the EMEA and the dossier's Rapporteurs that the CHMP considers the data available to date and provided in the Marketing Authorisation Application, not sufficient to allow the Committee to conclude on a positive benefit risk balance.

The Company believes that HDAC inhibitors are a valuable new class in anti-cancer therapy and is further developing vorinostat for the treatment of solid tumors and hematological malignancies. The Company confirms there is no impact for patients in ongoing clinical trials.

The Company will continue to supply vorinostat, registered in the US for the intended CTCL indication, to patients with CTCL in the compassionate use and named patient basis programmes in the EU.

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

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

Yours sincerely,