[redacted]

To: Dr. Tomas Salmonsson (CHMP Chairman)
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

[redacted]

Brussels, November 27, 2012

Subject: **Withdrawal of JENZYL (ridaforolimus 10 mg tablets)**
EMEA/H/C/02259

Dear Dr. Salmonsson,

I would like to inform you that, at this point of time, Merck Sharp and Dohme Ltd. has taken the decision to withdraw the application for the Marketing Authorisation of JENZYL (ridaforolimus, 10 mg tablets), which was intended to be used for the maintenance treatment of patients with soft tissue sarcoma or primary malignant bone tumor.

This withdrawal is based on the following reason: the CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance.

The Company believes that ridaforolimus is a valuable anti-cancer therapy and is further developing this compound in the oncology therapeutic area.

The Company confirms there is no impact for the patients in ongoing clinical trials

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 European Medicines Agency website.

Yours sincerely,

[redacted]

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