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MERCK

Dr Eric Abadie, CHMP Chairman
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8 February, 2011

Subject: **Withdrawal of Marketing Authorisation Application for MOVECTRO® (Cladribine 10 mg tablets) - EMEA/H/C/001197**
Applicant: Merck Serono Europe Limited

Dear Dr Abadie,

For and on behalf of Merck Serono Europe Limited (the "Applicant"), I write to inform you that the Applicant has decided to withdraw the application for Marketing Authorisation for MOVECTRO (cladribine 10 mg tablets), which was intended to be used for the treatment of Relapsing Remitting Multiple Sclerosis.

This withdrawal is made by reference to the CHMP's adopted opinion that the data available to date do not allow the Committee to conclude at present a positive risk/benefit balance for MOVECTRO in the proposed indication.

The Applicant understands that the CHMP opinion has no consequences for patients enrolled in ongoing clinical trials. In any event, the Applicant considers that these studies will likely generate additional clinical data to support a possible future regulatory submission in Europe.

For the avoidance of doubt, Merck Serono Europe Limited reserve the right to apply at a future date for granting of a Marketing Authorisation in this or other therapeutic indication(s) in respect of a medicinal product containing cladribine as the active ingredient.

The Applicant agrees that this letter can be published on the EMA website.

Yours sincerely,

[redacted]

Director, Global Regulatory Affairs
c/o Merck Serono Europe Limited

[redacted]