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NOVARTIS

Dr Eric Abadie
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

15 September 2010

Subject: Withdrawal of initial marketing authorisation application for Rasival, (aliskiren+valsartan), 150/160 mg, 300/320 mg film-coated tablets – EMEA/H/C/1191

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Novartis Europharm Limited has taken the decision to withdraw the application for Marketing Authorisation of Rasival (aliskiren+valsartan), 150/160 mg and 300/320 mg film-coated tablets, which was intended to be used for the treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of aliskiren and valsartan taken as single-component formulations at the same dose administered concurrently.

Novartis Europharm Limited is withdrawing the application based on the inability to address the CHMP request to provide additional data satisfying the relevant EU guidelines within the timeframe of the current procedure.

At the present time, there are no ongoing clinical trials with Rasival 150/160 mg, 300/320 mg film-coated tablets.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

Novartis Europharm Limited agrees for this letter to be published on the EMA website.

Yours sincerely,
Novartis Pharma AG
(on behalf of Novartis Europharm Ltd)