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Cc: Dr. P. de Graeff, MEB, Rapporteur
Dr. Concepcion Prieto Yerro, AEMPS, Co-Rapporteur
[redacted] EMA PTL

17 January 2013

Withdrawal of RUVISE (imatinib mesilate) 100 and 400 mg film-coated tablets, EMEA/H/C/002551

Dear Dr. Salmonsson,

We would like to inform you that Novartis has taken the decision to withdraw the application for Marketing Authorisation of RUVISE (imatinib mesilate) 100 and 400 mg film-coated tablets, which was intended to be used for adults as add-on therapy for the treatment of pulmonary arterial hypertension (PAH).

This decision was taken since additional data are required in order to address CHMP questions relating to the benefit/risk assessment of imatinib in PAH patients. These data will not be available within the timeframe allowed in the Centralised Procedure.

Patients participating in on-going open-label extension trials and who are benefiting from RUVISE can continue treatment as per the study protocols.

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

Novartis agrees for this letter to be published on the European Medicine Agency website.

Yours sincerely,

Novartis Pharma AG on behalf of Novartis Europharm Ltd.

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Global Program Regulatory Manager

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