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Date: 4th January 2018

Dr Tomas Salmonson
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Subject: Withdrawal of BALIMEK, (binimetinib), 15mg, film-coated tablet – initial Marketing Authorisation Application - EMEA/H/C/004052

Dear Dr Salmonson,

I would like to inform you that, at this point of time, following the Day180 list of outstanding issues and the clarification meeting with Rapporteur, Co-Rapporteur and EMA representative, Pierre Fabre Médicament has taken the decision to withdraw the application for Marketing Authorisation of BALIMEK (binimetinib), 15mg, film-coated tablet, which was intended to be used *"as monotherapy for the treatment of adult patients with unresectable or metastatic melanoma, with NRAS Q61 mutation"*.

This withdrawal is based on the CHMP consideration that the data provided did not provide a sufficient amount of evidence to conclude on a positive benefit risk balance in the above claimed indication at this time.

Pierre Fabre Médicament believes that there is an unmet medical need in NRAS melanoma patients who received prior immunotherapy (ies) but acknowledges the need to submit additional data for marketing authorisation approval in this population.

There are no consequences for patients currently included in clinical trials with binimetinib. This decision does not impact the ongoing development programme investigating binimetinib as a combination treatment in other indications.

Pierre Fabre Médicament would like to sincerely thank the (Co) Rapporteurs, EMA, PRAC and the CHMP for their time dedicated to reviewing this application and the valuable support and helpful guidance provided during the review process.

Pierre Fabre Médicament remains committed to the development of binimetinib in melanoma and across other tumour types and reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

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

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