

11 May 2020

Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

**Subject: Withdrawal of Erlotinib Accord 25/100/150 mg film-coated tablets -
EMEA/H/C/5071/0000**

Dear Dr. Harald Enzmann,

I would like to inform you that, at this point of time, Accord Healthcare S.L.U. has taken the decision to withdraw the application for Marketing Authorisation of Erlotinib Accord 25/100/150 mg film-coated tablets, which was intended to be used for:

Non-small cell lung cancer (NSCLC)

Erlotinib Accord is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR activating mutations.

Erlotinib Accord is also indicated for switch maintenance treatment in patients with locally advanced or metastatic NSCLC with EGFR activating mutations and stable disease after first-line chemotherapy.

Erlotinib Accord is also indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. In patients with tumours without EGFR activating mutations, Erlotinib Accord is indicated when other treatment options are not considered suitable.

When prescribing Erlotinib Accord, factors associated with prolonged survival should be taken into account.

No survival benefit or other clinically relevant effects of the treatment have been demonstrated in patients with Epidermal Growth Factor Receptor (EGFR)-IHC negative tumours.

Pancreatic cancer

Erlotinib Accord in combination with gemcitabine is indicated for the treatment of patients with metastatic pancreatic cancer.

When prescribing Erlotinib Accord, factors associated with prolonged survival should be taken into account.

No survival advantage could be shown for patients with locally advanced disease.

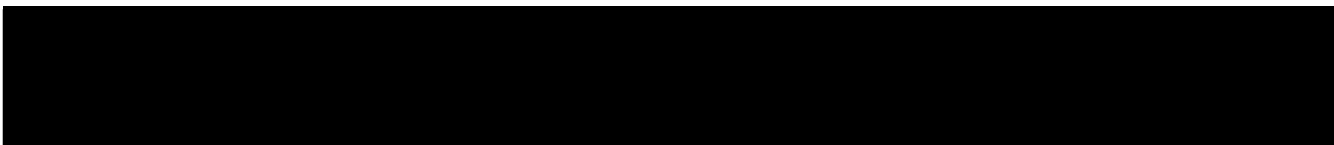
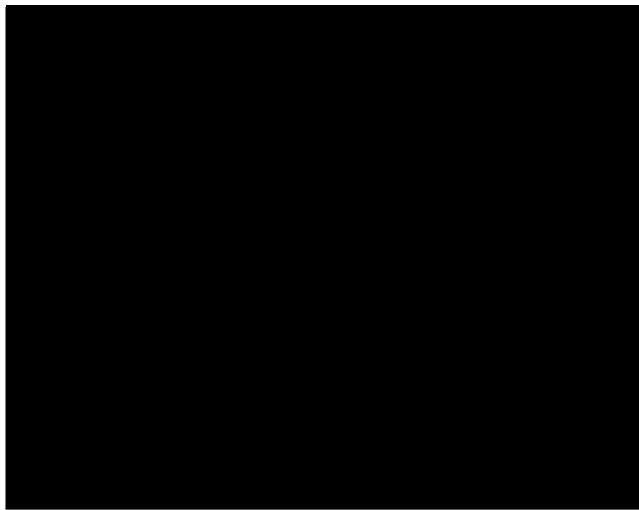
This withdrawal is based on the following reasons:

- Bioequivalence study data are not considered adequate to support marketing authorization of the medicinal product.

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 EMEA website.

Yours sincerely,



Accord Healthcare S.L.U. Inscrita en el R. M. Barcelona. Tomo: 41271. Folio: 1. Hacia 8379213. Inscrición 1. CIF: B65112930