

03 May 2016

Dr. Tomas Salmonson CHMP Chairman European Medicines Agency (EMA) 30 Churchill Place Canary Wharf London E14 5EU

Subject: Withdrawal of MAA for Xegafri (rociletinib) 125 mg and 250 mg film-coated tablets - EMA Procedure No. EMEA/H/C/004053

Dear Dr Salmonson,

We write to inform you that, at this point in time Clovis Oncology UK Ltd. has taken the decision to withdraw the application for Marketing Authorisation of Xegafri (rociletinib), 125 mg and 250 mg, film-coated tablets, which was intended to be used for the treatment of adult patients with mutant epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) who have been previously treated with an EGFR-targeted therapy and have the EGFR T790M mutation. This withdrawal is based on the revised business strategy for the product.

Clovis plans to terminate enrollment in all ongoing sponsored clinical studies of rociletinib but continue to provide drug to patients whose clinicians recommend continuing rociletinib therapy. In addition, patients currently receiving rociletinib through a compassionate use program can continue to receive treatment.

We reserve 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 EMA website.

Yours sincerely,



Clovis Oncology UK Ltd Sheraton House, Castle Park Cambridge, CB3 0AX United Kingdom

## CLOVIS ONCOLOGY

