Dr. Tomas Salmonson
Chair of Committee for Medicinal Products for Human Use
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

19 September 2016

Dear Dr Salmonson,

RE: Withdrawal of Zemfirza (Cediranib) 15 mg & 20 mg Film-Coated Tablets
Procedure No: EMEA/H/C/004003

It is with regret that AstraZeneca writes to inform you that, at this point in time, the Company wishes to withdraw the Marketing Authorisation Application for Zemfirza, proposed for the treatment of adult patients with platinum sensitive relapsed (PSR) ovarian cancer (including fallopian tube or primary peritoneal) in combination with platinum-based chemotherapy followed by maintenance monotherapy, from further assessment through the centralized procedure.

The assessment of the application has been managed by (Co)Rapporteurs Dr. Paula van Hennik from the Netherlands and Dr. Sinan B. Sarac from Denmark and has reached Day 181 of the procedure. The MAA is based on a single academically sponsored trial ICON6. Although AstraZeneca and the MRC (Sponsor of ICON6) provided extensive additional material to support the submission during review, questions remain at this late stage in the regulatory review process. Therefore, AstraZeneca believes the most appropriate course of action at this present time would be to withdraw the application from further assessment through the Centralised Procedure.

Cediranib remains an important part of AstraZeneca's ovarian cancer portfolio and this decision does not impact the ongoing primary development programme investigating cediranib as a combination treatment alongside potential medicines from the Company's extensive portfolio.AstraZeneca reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

AstraZeneca would like to thank the (Co)Rapporteurs, the EMA and the CHMP for the time dedicated to reviewing this application and the support provided to the Company during the review process.

I agree for this letter to be published on the EMA website.

Yours sincerely

AstraZeneca AB