[redacted]

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

12.10.2021

Subject: Withdrawal of Flynpovi, eflornithine/sulindac, 288.6 mg, /75 mg, Film-coated tablet EMEA/H/C/005043

Dear Dr. Harald Enzmann,

For the withdrawal of initial marketing authorisation application, I would like to inform you that, at this point of time, Cancer Prevention Pharma (Ireland) Limited has taken the decision to withdraw the application for Marketing Authorisation of Flynpovi, eflornithine/sulindac, 288.6 mg, /75 mg, Film-coated tablet (EMEA/H/C/005043), which was intended to be used as an adjunct to standard of care endoscopic surveillance for delaying the need for major surgery or resection of advanced adenoma in adult patients with familial adenomatous polyposis (FAP).

This withdrawal is based on the following reasons amongst others:

- identification of pre-clinical issue
- identification of clinical issues
- the CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance

We reserve the right to make further submissions at a future date in this or other therapeutic indication.

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

Sincerely,

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