To:
Head of Paediatric Medicines
European Medicines Agency
7 Westferry Circus
London E14 4HB
United Kingdom
paediatrics@ema.europa.eu

Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): Casopitant
Invented name: Zunrisa

Latest Decision number(s): 1) P/6/2009 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000154-PIP01-07 2) 3) 4)

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:
Nausea and vomiting

☒ has been discontinued
☐ has been suspended/put on long-term hold (with possible re-start at a later time)

for the following reason(s): *(tick all that apply)*

☐ (possible) lack of efficacy in adults
☐ (possible) lack of efficacy in children
☐ (possible) unsatisfactory safety profile in adults
☐ (possible) unsatisfactory safety profile in children
☐ commercial reasons (please specify:)
☐ manufacturing / quality problems
☐ other regulatory action (please specify:) *(e.g. suspension, revocation of M.A.)*
☒ other reason (please specify: Withdrawal of licence and discontinuation of clinical development)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:
The peadiatric development for Casopitant (Zunrisa) has been discontinued due to the withrawal of the Casopitant MAA in September 2009. Clinical development of casopitant in both adult and peadiatric populations has been discontinued.

Name and signature of the PIP contact point: Signature on file

Date: 5th Jan 2015

Contact for inquiries from interested parties: EU paediatric Plans - GSK

Telephone: +44 (0) 208 990 3650

Email: eu.paediatric-plans@gsk.com