To:

Head of Paediatric Medicines
European Medicines Agency
30 Churchill Place
London E14 5EU
United Kingdom
paediatrics@ema.europa.eu

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

Actives substances(s): osilodrostat (previously also referred to as 6,7-dihydro-5H-pyrrolo[1,2-c] imidazol-5-yl) - (benzo derivative))

Invented name: N/A

Latest Decision number(s): 1) P/177/2009 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000315-PIP01-08 2) EMEA- 3) EMEA- 4) EMEA-

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

hypertension

☒ 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:)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:

Clinical development in the area of aldosterone suppression/treatment of hypertension has been discontinued in view of the effect of osilodrostat on the ACTH/cortisol axis. No paediatric studies were ongoing in this therapeutic area at the time of discontinuation. Osilodrostat is now being developed in the treatment of endogenous hypercortisolism (EMEA-000315-PIP02-15).

Name and signature of the PIP contact point: Alexander Chesi

Date: 28-Sep-2017

Contact for inquiries from interested parties: Paediatric Enquiries, Novartis

Telephone: +41 61 324 11 11

Email: paediatric.enquiries@novartis.com