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): Olodaterol (hydrochloride)

Invented name: Striverdi Respimat

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

Corresponding PIP number(s): 1) EMEA-001965-PIP01-16 2) EMEA- 3) EMEA- 4) EMEA-

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

Treatment of cystic fibrosis

☒ 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: strategic reasons))

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

Boehringer Ingelheim has taken the decision to generally discontinue development of Olodaterol for treatment in cystic fibrosis. The decision has been taken based on strategic considerations. Striverdi Respimat has never been registered for treatment in cystic fibrosis in the EU Member States or any country in the EEA.

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

Date: 01 June 2018

Contact for inquiries from interested parties: Boehringer Ingelheim International GmbH

Telephone: +49 6132 77-8271

Email: paediatrics@boehringer-ingelheim.com