27 June 2013
EMA/CHMP/352675/2016
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): Indacaterol

Procedure No. EMEA/H/C/1121/PSUV/0023

Period covered by the PSUR: 1 December 2011 – 30 November 2012

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2016. Reproduction is authorised provided the source is acknowledged.

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Onbrez Breezhaler, Oslif Breezhaler and Hirobriz Breezhaler, the scientific conclusions of PRAC are as follows:

Intubation, hospitalisation and death due to asthma related events related to use in the asthma population is considered an important potential risk for indacaterol since it is a known class effect for long-acting $beta_2$-adrenergic agonists when used in asthma. No information is currently included in the SmPC for indacaterol for this risk. Indacaterol is only indicated for Chronic Obstructive Pulmonary Disease (COPD), which distinguishes its use from that of other, established Long-Acting Beta- Agonists (LABA) which also have approved asthma indications. However some information regarding this risk should be included in the product information for indacaterol. Furthermore, it is relevant to state in the SmPC that the risk has been observed with LABAs when used for the treatment of asthma. Therefore, in view of available data, the PRAC considers that inclusion of this information to the product information is warranted.

Long-acting beta agonist agents are known to potentially affect QTc intervals. Available data for indacaterol do not demonstrate a relevant effect of QT prolongation from a dedicated QT-study during development or from clinical trials in COPD (although patients with a medical history of long QT syndrome or long QT interval at baseline were excluded). Post-marketing reports for QT prolongation have been evaluated in the PSURs and have not reveal data indicating a causal relationship with indacaterol so far. Therefore, in view of the available data, the PRAC considers that changes to the product information were warranted to better reflect the current evidence for QT-prolongation with indacaterol.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisations

On the basis of the scientific conclusions for Onbrez Breezhaler, Oslif Breezhaler and Hirobriz Breezhaler the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing the active substance indacaterol is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisations should be varied.