



New data presented at ERS 2017 on flutiform[®] k-haler[®] (*fluticasone propionate and formoterol*), Mundipharma's novel breath-triggered aerosol inhaler

- flutiform k-haler achieved high levels of lung deposition of over 44% of delivered dose
- Plume force of flutiform k-haler was compared with fluticasone propionate/salmeterol xinafoate delivered via the Seretide[®] Evohaler[®] pMDI and Sirdupla[®] pMDI devices
- Pharmacokinetic studies show efficacy and safety profile of new flutiform k-haler device would be comparable to flutiform pMDI device

CAMBRIDGE, 10 SEPTEMBER 2017 – Mundipharma today announced new data from four studies demonstrating efficient drug delivery characteristics with flutiform[®] k-haler[®], a novel, breath-triggered inhaler, currently in development.

The efficacy of inhaled asthma treatments is dependent on adequate deposition of the drug in the lungs. Poor or improper inhaler technique in asthma patients can lead to critical inhaler errors and is associated with reduced disease control,^{1,2} worse asthma outcomes³ and an increase in hospital visits, compared to patients with good inhaler technique.¹

The flutiform k-haler takes its name from a unique kinked valve which removes the need for coordination, with only gentle inhalation required to trigger the aerosol.

Details of the four flutiform k-haler presentations

The first study examined the pulmonary deposition of the flutiform k-haler device (125/5 microgram) using gamma scintigraphy and showed that in patients with asthma, high levels of lung deposition of over 44% of the delivered dose were achieved.⁴

A second *in vitro* study compared the plume force of flutiform k-haler 125/5µg with fluticasone propionate/salmeterol xinafoate 125/25µg (FP/SAL) from the Seretide[®] Evohaler[®] pMDI; and 125/25µg

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FP/SAL from the Sirdupla® pMDI over distances of 25-95mm. 60-95mm represents the typical distance between the inhaler and back of the throat. ⁵ Plume characteristics of aerosol devices may affect drug delivery to the lungs and impaction at the back of the throat.⁵

The final two single dose, cross-over pharmacokinetic studies assessed how pulmonary bioavailability and systemic exposure of fluticasone propionate and formoterol 125/5µg of flutiform k-haler compared to Mundipharma's existing flutiform pMDI device when administered in healthy adults with or without a spacer. These data suggest that the efficacy (based on pulmonary bioavailability) and safety (based on total systemic exposure) profile of the new device would be comparable to the registered flutiform pMDI device. ^{6,7}

Jonathan Marshall, Head of Medical Insights, Mundipharma International Limited commented: *"The studies presented at this year's ERS conference demonstrate how effective the k-haler is at delivering fluticasone propionate/formoterol to the lungs, achieving high levels of lung deposition in patients with asthma. If approved, flutiform k-haler would offer a new device choice for certain patients with asthma."*

-Ends-

Notes to editors:

For further information please visit:

<http://www.mundipharma.com/Press/RespiratoryResources/background>

www.flutiform.com/medical-media/resource-centre

About the Mundipharma network

The Mundipharma global network of privately-owned independent associated companies was founded in 1956 by doctors, and now operates in over 120 countries worldwide. We are focused on developing business partnerships to identify and accelerate meaningful technology across an increasingly diverse portfolio of therapy areas including respiratory, oncology, pain, and biosimilars. Consistent with our entrepreneurial heritage, we like to think we see what others don't by challenging conventional wisdom and asking different and challenging questions. By working in partnership with all our stakeholders, the Mundipharma network develops medicines that create value for patients, payers and wider healthcare systems.

For more information please visit: www.mundipharma.com.

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About flutiform pMDI

In Europe, flutiform pMDI is licensed for the regular treatment of asthma when use of a combination product (an inhaled corticosteroid [ICS] and a long-acting β 2-agonist [LABA]) is appropriate: for patients not adequately controlled with an ICS and an 'as required' inhaled short-acting β 2-agonist or for patients already adequately controlled on both an ICS and a LABA. It is available in countries across Europe including the UK, Germany, France, Spain, Netherlands and Italy. flutiform pMDI is available in 50/5 μ g and 125/5 μ g strengths for adults and adolescents; 250/10 μ g strength for adults only.⁸

About asthma

Asthma is a chronic inflammatory disorder of the airways which leads to recurrent episodes of wheezing, breathlessness, chest tightness and coughing. Patients with poorly managed asthma are at an increased risk of exacerbations, hospitalisation and death. Poorly managed asthma can also have a huge impact on a person's quality of life and day-to-day activities.⁹

About Gamma Scintigraphy

Gamma scintigraphy is an imaging technique using radioisotopes attached to drugs that travel to a specific organ or tissue and the emitted gamma radiation is captured by external detectors. This enables the direct visualisation and quantification of events occurring in vivo, in real time.

About Vectura

About Vectura

Vectura, a FTSE250 company listed on the London Stock Exchange (LSE: VEC), is an industry-leading device and formulation business for inhaled airways products offering a uniquely integrated inhaled drug delivery platform. With its extensive range of device and formulation technologies, integrated capabilities and collaborations, Vectura is a leader in the development of inhalation products, increasing its ability to help patients suffering from respiratory diseases.

Vectura has eight inhaled, four non-inhaled and ten oral products marketed by partners with growing global royalty streams. The group has a diverse portfolio of drugs in clinical development, including a number of novel and generic programmes which are partnered with several global pharmaceutical and biotechnology companies including Hikma, Novartis, Sandoz, Mundipharma, Kyorin, Baxter, GSK, UCB,

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Ablynx, Grifols, Bayer, Chiesi, Almirall, Janssen, Dynavax and Tianjin KingYork along with two wholly owned nebulised development programmes.

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- ⁴ Kappeler D, et al. Lung deposition of fluticasone propionate/formoterol administered via a breath-triggered inhaler. Abstract presented at European Respiratory Society (ERS) annual congress, Milan, Italy 2017 September 9- 13 [PA522]
- ⁵ Tuohy J, et al. Plume spray force of three HFA-propelled ICS/LABA combination inhalers. Abstract presented at European Respiratory Society (ERS) annual congress, Milan, Italy 2017 September 9- 13 [PA524]
- ⁶ Bell D et al. Relative pulmonary bioavailability (BA) of fluticasone propionate/formoterol (FP/FORM) via pressurised metered-dose inhaler (pMDI) and a novel breath-triggered inhaler (BTI). Abstract presented at European Respiratory Society (ERS) annual congress, Milan, Italy 2017 September 9- 13 [PA523]
- ⁷ Bell D et al. Systemic bioavailability (BA) and pharmacodynamics (PD) of fluticasone propionate/formoterol (FP/FORM) via pressurised metered-dose inhaler (pMDI) or a novel breath-triggered inhaler (BTI). Abstract presented at European Respiratory Society (ERS) annual congress, Milan, Italy 2017 September 9- 13 [PA3950]
- ⁸ flutiform SmPC
- ⁹ European Respiratory Society. The European Lung White Book. 2013. Available at: <http://www.erswhitebook.org/>