FOR EUROPEAN TRADE & FINANCIAL MEDIA

Mundipharma announces the positive outcome of the European Decentralised Procedure (DCP) for ***flutiform®*** ***k-haler®*****,** a novel treatment for adolescents and adults with asthma

CAMBRIDGE, 04 OCTOBER 2017 – The Mundipharma network of independent associated companies announced today the positive outcome of the European Decentralised Procedure (DCP) for ***flutiform®*** ***k-haler®***, a novel asthma treatment for adults and adolescents (aged 12 years and older) where the use of a combination product (inhaled corticosteroid [ICS] and long-acting β_2-agonist [LABA]) is appropriate. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) acted as the Reference Member State for the DCP, which covers 18 countries across Europe.

k-haler is an award-winning[1] aerosol device with a simple breath-triggered mechanism, activated with a low inspiratory force, which is designed to make it easier for patients to use correctly, including those who may find other devices challenging to use. Sub-optimal asthma control remains a major problem for patients in Europe[2] and errors in inhaler technique are contributing to poor outcomes, leading to unnecessary healthcare costs.[3]

flutiform k-haler contains the same combination of fluticasone propionate and formoterol fumarate (50/5µg and 125/5µg strengths) as Mundipharma's existing asthma maintenance combination treatment, ***flutiform*** pMDI (pressurised metered dose inhaler).[4] The efficacy and tolerability of ***flutiform*** pMDI, launched five years ago across Europe and Asia-Pacific region, is supported by extensive clinical and real-world evidence.[4,5,6,7,8]

"Mundipharma has listened to patients and doctors to understand the day-to-day challenges of managing asthma. Our drug delivery expertise and approach to provide a range of patient focused solutions is aimed at helping to improve outcomes and enable people with respiratory diseases to breathe better," said Jonathan Marshall, Head of Medical Insights, Mundipharma. *"This positive outcome is an important step in the regulatory process. We can now begin to apply for national approvals and reimbursement in the European countries covered by this procedure."*

In Europe, approximately 30 million people under the age of 45 have asthma.[9] Poor asthma control is associated with increased risk of exacerbations, impaired quality of life, increased healthcare utilisation

and reduced productivity.[2] New research indicates that errors in inhaler technique are frequent (made by over 30% of patients in some cases) and can reduce control of asthma.[3] Choosing the right inhaler type for each patient can help to reduce the number of critical inhaler errors and ultimately improve patient health.[3]

The ***k-haler*** device's patented technology has the potential to be suitable for a range of inhaled products and forms a platform for future drug development by Mundipharma.

-Ends-

Notes to editors:

For further information please visit:

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

http://www.flutiform.com/medical-media

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.

About ***flutiform***

In Europe, ***flutiform*** is licensed for the regular treatment of asthma in patients aged 12 years and over when use of a combination product (an inhaled corticosteroid [ICS] and a long-acting β2-agonist [LABA]) is appropriate: for patients not adequately controlled with an ICS and an 'as required' inhaled short-acting β2-agonist or for patients already adequately controlled on both an ICS and a LABA. It is available in 20 countries across Europe including the UK, Germany, France, Spain, Netherlands and Italy. ***flutiform*** is available in 50/5µg and 125/5µg strengths for adults and adolescents; 250/10µg strength for adults only.

Job code: MINT/RESP-17007
Date of preparation: October 2017

FOR EUROPEAN TRADE & FINANCIAL MEDIA

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]

For further information please contact:

Tiffany Wright

Strategic Communications Lead, Mundipharma International Ltd

E-mail: Tiffany.Wright@mundipharma.com

Tel: +44 (0) 7773 199 422

Nicola Lilley

Account Director, Havas SO

E-mail: Nicola@sowhatglobal.com

Tel: +44 (0) 7983 128 712

References:

[1] Spark Awards. ***k-haler.*** http://www.sparkawards.com/galleries/index.cfm?entry=1DD7D361-0D98-03C9-7058504DE3B54B93 Last accessed September 2017

[2] Price D, et al. Asthma control and management in 8,000 European patients: the REcognise Asthma and LInk to Symptoms and Experience (REALISE) survey. npj Primary Care Respiratory Medicine 2014. doi:10.1038/npjpcrm.2014.9

[3] D.Price *et al.* "Inhaler errors in the CRITIKAL Study: type, frequency and association with asthma outcomes". *Journal of Allergy and Clinical Immunology: In Practice. 2017* DOI: http://dx.doi.org/10.1016/j.jaip.2017.01.004

[4] *flutiform* SmPC

[5] Bodzenta-Lukaszyk A, R Buhl, *et al.* Fluticasone/formoterol combined in a single aerosol inhaler vs budesonide/formoterol for the treatment of asthma: a non-inferiority trial. Eur Respir J 2011a;38:153s

[6] Bodzenta-Lukaszyk A, Dymek A *et al.* Fluticasone/formoterol combination therapy is as effective as fluticasone/salmeterol in the treatment of asthma, but has a more rapid onset of action: an open-label, randomized study. BMC Pulm Med J. 2011;11:28

[7] Bodzenta-Lukaszyk A, Pulka *et al.* Efficacy and safety of fluticasone and formoterol. Respir Med J. 2011;105(5):674-82

[8] Backer V, et al. Real-world study to evaluate the safety and effectiveness of fluticasone propionate/formoterol (FP/FORM) in patients with asthma. Abstract FLT9503, European Respiratory Society (ERS) 2017, Milan

[9] European Respiratory Society. The European Lung White Book. 2013

Job code: MINT/RESP-17007

Date of preparation: October 2017