

flutiform[®] k-haler[®], a Novel Treatment for Adolescents and Adults with Asthma, now Available in Europe

- **flutiform k-haler** is now available in Europe as an asthma treatment for adults and adolescents (aged 12 years and older)¹
- Research indicates that many patients make errors with their inhalers and this is associated with poor asthma control and increased exacerbations²
- The **k-haler** device is a simple breath-actuated, or breath-triggered, inhaler, ICS/LABA combination inhaler designed with the aim to make it easier for patients to use correctly

CAMBRIDGE, 10 September 2018 – The Mundipharma network of independent associated companies today announces that **flutiform k-haler** is now available in Europe for adults and adolescents (aged 12 years and older) with asthma where the use of a combination product (inhaled corticosteroid [ICS] and long-acting β_2 -agonist [LABA]) is appropriate.¹ NAPP has launched **flutiform k-haler** in the UK, marking the first country where the product is available, and further launches are anticipated across European countries in the coming months. **flutiform k-haler** was approved through the European Decentralised Procedure (DCP), with the UK's Medicines and Healthcare products Regulatory Agency (MHRA) acting as the Reference Member State for the DCP, which covers 18 countries across Europe.

k-haler is an award-winning³ breath-triggered aerosol device utilising a patented 'kinked' valve – the k-valve™ which has been designed with the aim to make it easier for patients to use correctly. **flutiform k-haler** will be the first breath-triggered ICS/LABA combination aerosol inhaler available in Europe. **flutiform k-haler** contains fluticasone propionate and formoterol and is available in two strengths (50/5 μ g and 125/5 μ g). It is administered as two puffs (actuations) twice daily.¹

“This launch is great news for patients with asthma in Europe, who will have the potential to benefit from this new inhaler,” commented Alberto Martinez, President and CEO, Mundipharma International Limited. *“Patients can struggle to use their inhalers correctly and make critical errors which is associated with poor asthma control and increased exacerbations. This simple breath-triggered inhaler has been designed with patients in mind, requiring only a gentle inhalation to trigger the dose release, with the aim to help patients reduce critical errors and improve long-term outcomes.”*

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flutiform k-haler is the same combination as Mundipharma's existing maintenance combination treatment, **flutiform** pMDI (pressurised metered dose inhaler).¹ The efficacy and tolerability of **flutiform** pMDI is supported by extensive clinical evidence and real-world use for over five years across Europe and Asia-Pacific regions.^{4,5,6,7}

Studies have shown effective drug delivery with the **k-haler** device. In a gamma scintigraphy study, **flutiform k-haler** delivered a mean total lung deposition of 43% of the metered dose in asthma patients.⁸ Another study also highlighted ease of use with **flutiform k-haler**; almost all patients (93%) performed correct handling of the **k-haler** device at their first or second attempt after training.⁹

Asthma is a debilitating long-term health condition that remains a major problem for almost 30 million children and adults under the age of 45 in Europe despite a range of available treatments.¹⁰ Sub-optimal asthma control remains a major problem for patients in Europe.¹¹ Poor asthma control is associated with increased risk of exacerbations, impaired quality of life, increased healthcare utilisation and reduced productivity.¹¹ Research indicates that many patients make errors with their inhalers and this is associated with poor asthma control and increased exacerbations.² Ongoing training may help to reduce critical errors.²

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 asthma to breathe better.

-Ends-

Notes to editors:

For further information please visit:

<https://www.mundipharma.com/media/media-libraries/>

<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

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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 k-haler*

flutiform k-haler is 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.¹ It is a unique breath-triggered inhaler utilising a patented 'kinked' valve – the k-valve™. The device is 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. The *k-haler* device's patented technology has the potential to be suitable for a range of inhaled products.

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.¹²

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™ K-VALVE is a trade mark of Mundipharma

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¹ *flutiform k-haler* Summary of Product Characteristics

² Price D, 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>

³ A' Design Award & Competition. K-Haler Inhaler. Available at:

<https://competition.adesignaward.com/design.php?ID=61400> Last accessed August 2018

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⁶ Bodzenta-Lukaszyk A, Pulka et al. Efficacy and safety of fluticasone and formoterol. *Respir Med J*. 2011;105(5):674-82

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⁹ Bell D, L Mansfield, M Lomax. A Randomized, Crossover Trial Evaluating Patient Handling, Preference, and Ease of Use of the Fluticasone Propionate/Formoterol Breath-Triggered Inhaler. *J Aerosol Med Pulm Drug Deliv* 2017a;30(6):425-34.

¹⁰ European Respiratory Society. *The European Lung White Book*. 2013

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