flutiform® receives a positive opinion in Europe for the Treatment of Children with Asthma

- ***flutiform***® will soon be available in Europe as a maintenance asthma treatment for children aged 5 to <12 years where the use of an ICS/LABA combination is appropriate[1]
- Asthma is the most common chronic disease in childhood,[2] and despite the availability of several paediatric treatment options, uncontrolled asthma is still common amongst children[3]
- ***flutiform***® has been available in Europe for the treatment of adolescents (≥12 years old) and adults since 2012, and has been shown to have a strong tolerability profile from six years of extensive clinical evidence and real-world use[1,4,5,6,7]

CAMBRIDGE, 7 November 2018 – The Mundipharma network of independent associated companies today announced that the European Decentralised Procedure (DCP) licence variation application for ***flutiform***®, extending the indication to the treatment of asthmatic children, has closed with a positive opinion. ***flutiform***® is a combination of fluticasone propionate and formoterol in a single pressurised metered dose inhaler (pMDI), otherwise known as a press and breathe aerosol inhaler. It is now indicated at a dose of two puffs (actuations) 50/5 µg for regular twice-daily, maintenance treatment of asthma in children aged 5 to <12 years when a combination of an inhaled corticosteroid (ICS) and a long-acting β2-agonist (LABA) is appropriate.[1]

flutiform® has been available in Europe for the treatment of asthma in adults and adolescents (≥12 years old) since 2012 and has a tolerability profile supported by extensive clinical evidence and real-world use for six years across Europe and Asia-Pacific regions in this age group.[1,4,5,6,7]

"We are delighted that the combination aerosol ***flutiform***® *has now been licenced for use in children aged 5 to <12 years in addition to the current indication for adolescents and adults," said Catriona Cutting, Head of Regulatory Strategy, Mundipharma. "Asthma affects all aspects of children's and their families' lives and new treatment options for paediatric asthma are still very much needed."*

Asthma is the most common chronic disease in childhood[2] and represents a major health burden.[8] Despite the availability of several paediatric treatment options, uncontrolled asthma is still common in children[3] and morbidity from the condition is a major health burden for patients, their families and society.[8] Poorly controlled asthma in children is associated with time off school, exacerbations and days

in hospital.[9] Recent studies suggest that poor asthma control may have a greater impact on children than previously thought, including important long-term consequences such as an increased risk of lifestyle-associated diseases and poorer school performance.[10]

*"The paediatric licence indication for **flutiform**® is part of Mundipharma's commitment to provide new treatments to help improve the lives of people affected by asthma,"* said Alberto Martinez, President and CEO, Mundipharma International. *"The use of this combination is now well established in adults and adolescents, and we are delighted that following this positive opinion we will also be able to offer this combination for the treatment of paediatric patients."*

The licence variation of ***flutiform***® for use in children was based on efficacy and safety data from two 12-week paediatric studies, which demonstrated that the treatment administered as two puffs (actuations) of 50/5 µg dose b.i.d., was non-inferior on lung function endpoints to the established combination therapy, fluticasone propionate/salmeterol, and had a similar tolerability profile. In addition, during a 24-week extension phase of one of the studies, lung function improvements compared with baseline were sustained.[11] The 24-week extension phase also showed that children receiving ***flutiform***® had growth rates and plasma cortisol levels within the normal ranges. A 28-day knemometry study further found that ***flutiform***® did not suppress lower leg growth rate compared with baseline.[11]

flutiform® is an easy-to-use inhaler, which can be used effectively with or without a spacer (use of a spacer is advised for children who may find coordination of actuation with inspiration difficult).[12] The recommended dose of ***flutiform***® in children is two puffs (actuations) 50/5 µg twice daily (BID).

-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, diabetes, 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 global 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 licenced for regular twice-daily, maintenance treatment of asthma in patients aged 5 years and over when use of a combination product (an inhaled corticosteroid [ICS] and a long-acting β2-agonist [LABA]) is appropriate. As of November 2018, it is available in 21 countries across Europe including the UK, Germany, France, Spain and Italy. ***flutiform***® is available in 50/5µg strength for children aged 5 to <12 years, in 50/5µg and 125/5µg strengths for adults and adolescents and 250/10µg strength for adults only.

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.[13]

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