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Largest ever flutiform® study confirms effectiveness and tolerability in real-world clinical practice: Findings from A*ff*IRM study to be presented at ERS 2017

- First presentation of largest ever real-world flutiform® study at European Respiratory Society International Congress involving over 2,500 patients
- Proportion of patients with well-controlled asthma more than doubled 12 months after switching to flutiform pMDI

CAMBRIDGE, 11 SEPTEMBER 2017 – New real-world data to be presented at the European Respiratory Society (ERS) annual congress in Milan, Italy, will show that the proportion of patients with well-controlled asthma more than doubled 12 months after switching to flutiform pMDI (pressurised metered dose inhaler) compared with baseline.[1] flutiform (fluticasone propionate/formoterol) is indicated for use as a maintenance treatment for asthma patients aged 12 years and older where ICS/LABA therapy is appropriate.

"*This large study further extends the body of evidence for flutiform, demonstrating its safety and effectiveness profile in patients in real life clinical practice with improved asthma control and a reduction in exacerbations compared with baseline*" commented Professor David Price, Chair of Primary Care Respiratory Medicine at the University of Aberdeen, Aberdeen, UK. "*Real-world evidence like this is essential to complement data from randomised controlled trials (RCTs) by evaluating outcomes in asthma patients in everyday clinical practice, as RCTs investigate a subgroup of the asthma population and adherence tends to be unusually high*."

Assessment of **fl**uticasone propionate/**f**ormoterol **I**n **R**eal life **M**aintenance treatment (A*ff*IRM) is the largest study to date of flutiform, with over 2,500 patients enrolled, and is part of A*ff*inity, Mundipharma's international collaborative research programme for flutiform.

In this one-year, non-interventional study of 2,539 asthma patients, more than two thirds of patients had switched from another ICS/LABA (either a fixed dose combination or free combination of ICS plus LABA).[1] The safety profile of flutiform pMDI in practice was consistent with that demonstrated in clinical

trials. Secondary analyses demonstrated that the proportion of patients with controlled asthma increased from 29.4% at baseline to 67.4% (last observation carried forward) and the mean total Asthma Control Test score increased from 16.3 to 20.4.[1] In the year prior to enrolment, 64.2% patients were free from severe asthma exacerbations compared with 90.2% during the study period. flutiform pMDI was associated with improvements from baseline in Asthma Quality of Life scores, adherence and physician/patient satisfaction.[1]

Sub-optimal asthma control remains a major problem in Europe, with many patients experiencing largely preventable symptoms that disrupt their daily lives.[2] Research suggests that only 20% of patients in Europe have controlled asthma according to the GINA definition.[2] In addition, poor or improper inhaler technique in asthma patients can lead to critical inhaler errors and are associated with reduced disease control,[3,4] worse asthma outcomes[5] and an increase in hospital visits.[3]

-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.

About flutiform

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In Europe, flutiform is licensed for the regular treatment of asthma 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 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.[6]

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.[7]

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

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