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New Sandoz patient-centric inhaler now available to treat adults with COPD

- *Novel inhaler approved for adults with chronic obstructive pulmonary disease (COPD)*
- *Combination of salmeterol and fluticasone, a long established and proven treatment for COPD¹*
- *Award-winning intuitive delivery device could improve patient treatment adherence and clinical outcomes*
- *Adherence to inhaled medication is significantly associated with reduced risk of death and admission to hospital due to exacerbations in COPD²*

Frimley, Surrey, November 19, 2015 – AirFluSal® Forspiro® (500mcg fluticasone propionate / 50mcg salmeterol) a new twice-daily inhaler for patients with COPD has been launched today in the UK. AirFluSal Forspiro has been developed with patients specifically for patients.³ Evidence shows that patients find it intuitive and easy to use,³ which could lead to improved patient outcomes through improved treatment adherence.^{4,5,6,7}

The combination of fluticasone propionate and salmeterol is a long established and proven treatment for the symptomatic treatment of COPD¹ and in addition to being 20% cheaper than Seretide Accuhaler,⁸ AirFluSal is delivered via Forspiro, a new device that has been developed with usability testing from the intended patient population.³

COPD is the second most common cause of emergency admissions to hospital and one of the most costly inpatient conditions to be treated by the NHS.⁹ In 2010, there were 115,000 emergency COPD-related hospital admissions in England costing the NHS £287m.¹⁰ Many of these hospital admissions could be prevented by reducing the risk of exacerbations through improving treatment adherence to inhaler medicine.²

Despite inhaled treatment, many COPD patients are not controlling their symptoms and incorrect inhaler technique has been recognised as a significant contributor.³ In fact, up to 94% of people are said not to use their inhaler device correctly.⁵ In addition, there have been cases of patients missing doses, as they are unsure if they have already taken their medication.¹¹ These combined adherence barriers can result in increased rates of COPD patient morbidity, hospitalisations and possibly mortality, as well as reduced quality of life.⁵

It has been acknowledged that the design of the inhaler contributes significantly to the patient's adherence to treatment⁴ and that a device with feedback mechanisms, which guides patients through the correct handling technique may reassure them that the dose has been taken and help ensure correct use of the inhaler, thereby helping to improve management of COPD.⁵

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Medienmitteilung

Communiqué Aux Médias

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Developed in collaboration with patients,³ the Forspiro device provides several features that enable the device to be easy-to-use and provide feedback mechanisms to offer the patient reassurance that the dose has been administered, such as:³

- A dose counter to see the remaining available doses
- A transparent feedback window showing the empty blisters which enables patients to see they have taken each dose
- Tear off foil strip enabling patients to ensure they have taken two doses per day
- A simple lever arm to load the dose

In a study, 11 out of 12 patients who had been given the Forspiro device for the first time and with limited instruction, rated Forspiro as either 'very easy' or 'fairly easy' to use for 'overall ease of use' and for 'ease of determining the number of doses left', and all 12 patients rated Forspiro as 'very easy' or 'fairly easy' to use for 'ease of preparing a dose' and 'ease of removing used blisters'.³

Dr Richard Russell, consultant respiratory physician, Southern Healthcare NHSFT, Lymington Hospital, Hampshire says *"It is recognised by healthcare professionals that lack of adherence to treatment through incorrect inhaler use is a serious problem when treating patients with COPD. This leads to an increased risk of exacerbation, which could contribute to further deterioration of their condition and an increased burden to the NHS. Any new device that could help improve treatment adherence will be warmly received by the medical community."*

The Forspiro device was developed at Aeropharm GmbH in Rudolstadt, Germany, Sandoz' global respiratory Center of Excellence. Sandoz partnered with UK-based Vectura, a respiratory product development company, in the design and development of the product. The innovative and intuitive to use design of the inhaler was awarded the Red Dot Product Design award in 2011, an internationally recognised quality seal awarded by the Design Zentrum Nordrhein Westfalen in Essen, Germany.¹² It was also more recently awarded the Alufoil Trophy earlier this year, due to the specially designed alufoil blister strip that gives the powder a longer shelf life.¹³

Stephan Eder, Country Head UK and Ireland says, *"The launch of AirFluSal® Forspiro® strengthens our respiratory portfolio and is our commitment to COPD patients in the UK. We believe AirFluSal Forspiro has the potential to have a positive impact not only for patients, but to generate savings for the NHS."*

Ends

About AirFluSal®

AirFluSal contains a combination of a long-acting beta-2-agonist (salmeterol) and a corticosteroid (fluticasone). Salmeterol is a selective, long-acting beta-2-adrenoceptor agonist.

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Fluticasone is a glucocorticoid anti-inflammatory. It is delivered twice daily via a dry power inhaler device Forspiro.¹⁴

AirFluSal has been approved for use in the symptomatic treatment of adult patients with COPD with a FEV₁ <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy.¹⁴

About COPD

- Chronic obstructive pulmonary disease (COPD) is a condition where the airways become inflamed and the air sacs in the lungs are damaged, causing the airways to become narrower, making it harder to breathe in and out¹⁵
- Three million people in the UK are thought to have COPD, yet over two million of these remain undiagnosed⁹
- On average there are 115,000 COPD emergency hospital admissions annually,¹⁰ making COPD the second largest cause of emergency admissions in the UK and one of the most costly inpatient conditions treated by the NHS⁹
- Since 2008, COPD related emergency hospital admissions have risen by 13%¹⁶
- Each year around 30,000 people in the UK die from COPD, which is the fifth biggest cause of death in the UK⁹
- The direct cost of COPD to the UK health system is estimated to be approximately £810-£930 million¹⁷ and it is estimated that the cost to the UK economy from lost productivity is over £3.8 billion⁹

About Sandoz

Sandoz, a division of Novartis, is a global leader in generic pharmaceuticals, driving sustainable access to high-quality healthcare. Sandoz employs more than 26,000 people worldwide and supplies a broad range of affordable, primarily off-patent products to patients and customers around the globe.

The Sandoz global portfolio comprises approximately 1,100 molecules, which accounted for 2014 sales of USD 9.6 billion. Sandoz holds the global #1 position in biosimilars as well as in generic anti-infectives, ophthalmics and transplantation medicines.

Nearly half of Sandoz's portfolio is in differentiated products – products that are scientifically more difficult to develop and manufacture than standard generics.

In addition to strong organic growth since consolidating its generics businesses under the Sandoz brand name in 2003, Sandoz has consistently driven growth in selected geographies and differentiated product areas through a series of targeted acquisitions.

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References

- ¹ Seretide Accuhaler SmPC <https://www.medicines.org.uk/emc/medicine/2317> Last accessed November 2015
- ² Vestbo, Jørgen, et al. "Adherence to inhaled therapy, mortality and hospital admission in COPD." *Thorax* 64.11 (2009): 939-943
- ³ Virchow, J. Christian, et al. "Identifying the features of an easy-to-use and intuitive dry powder inhaler for asthma and chronic obstructive pulmonary disease therapy: results from a 28-day device handling study, and an airflow resistance study." *Expert opinion on drug delivery* 11.12 (2014): 1849-1857.
- ⁴ Restrepo, Ruben D., et al. "Medication adherence issues in patients treated for COPD." *International journal of chronic obstructive pulmonary disease* 3.3 (2008): 371.
- ⁵ Lavorini, Federico, et al. "Effect of incorrect use of dry powder inhalers on management of patients with asthma and COPD." *Respiratory medicine* 102.4 (2008): 593-604
- ⁶ Newman, S. P. "Inhaler treatment options in COPD." *European Respiratory Review* 14.96 (2005): 102-108
- ⁷ Kuna, Piotr, et al. "Randomized equivalence trial: A novel multidose dry powder inhaler and originator device in adult and adolescent asthma." *Allergy and Asthma Proceedings*. Vol. 36. No. 5. OceanSide Publications, Inc, 2015.
- ⁸ Mims, <http://www.mims.co.uk/drugs/respiratory-system/asthma-copd/seretide-accuhaler>. Last accessed November 2015
- ⁹ Department of Health. An outcomes strategy for people with chronic obstructive pulmonary disease (COPD) and asthma in England. 2011.
- ¹⁰ Dr Foster Intelligence. The GP Practice Index, Second Edition. Exploring variation in COPD care and cost. 2010.
- ¹¹ Bourbeau J, Bartlett SJ. Patient adherence in COPD. *Thorax* 2008; 63:831-838
- ¹² Red Dot Design Award. <http://red-dot.de/pd/online-exhibition/work/?lang=en&code=2011-14-3170&y=2011&c=167&a=0>. Last accessed November 2015.
- ¹³ Alufoil Trophy 2015: The winners. <http://www.alufoil.org/alufoil-trophy-2015.html> Last accessed November 2015
- ¹⁴ AirFluSal Forspiro SmPC <https://www.medicines.org.uk/emc/medicine/31088> Last accessed November 2015
- ¹⁵ British Lung Foundation. COPD: living with chronic obstructive pulmonary disease. 2014
- ¹⁶ National COPD Audit Programme. COPD: Who cares? Royal College of Physicians and British Thoracic Society. November 2014
- ¹⁷ NICE Clinical Guideline. National Clinical Guideline Centre. Chronic obstructive pulmonary disease: management of chronic obstructive pulmonary disease in adults in primary and secondary care. London: National Clinical Guideline Centre. 2010.