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### Chronic obstructive pulmonary disease Novel anti-inflammatory agent reduces exacerbations

**VIENNA** - An oral, once-daily anti-inflammatory agent that inhibits the enzyme phosphodiesterase-4 (PDE4) improves lung function and reduces exacerbations in patients with moderate to severe chronic obstructive pulmonary disease (COPD).

Data from four studies presented at the *19th Annual Congress of the European Respiratory Society* and published simultaneously in a special COPD edition of *The Lancet* not only show a significant improvement in lung function but also a significant reduction in exacerbation rates.

Two 6-month trials and two 12-month trials involved more than 4000 patients in 10 countries.

In COPD, a chronic inflammatory process contributes to structural changes in the airways, causing airflow obstruction and ultimately leading to a decline in lung function and symptoms such as chronic cough and excessive production of mucous, as well as dyspnea. In addition, episodes of worsening of the patient's symptoms from his or her usual stable state (so-called exacerbations), usually triggered by respiratory infections, are an important cause of morbidity and mortality in COPD patients. While cigarette smoking and other inhalative irritants are thought to activate immune cells such as macrophages, initiating the disease, in later stages the disease progresses even upon cessation of smoking. The initial accumulation of inflammatory cells is followed by structural damage to air space and obstruction to airflow.

Although asthma and COPD are both characterized by inflammation, the two conditions have very different origins and responses to treatment. In contrast to asthma, in COPD both the inflammatory process and the airflow limitation are poorly reversible.

By inhibiting an enzyme central to the inflammatory process in COPD, this therapeutic approach aims at targeting the pathogenetic mechanism of chronic obstructive airways disease rather than merely giving symptomatic relief. It is also beneficial when combined with traditional symptomatic medications for COPD.

Press Release

“When the PDE4 inhibitor roflumilast is co-administered with long-acting bronchodilators, the combination may add beneficial effects”, explain **Professor Leonardo Fabbri**, MD, University of Modena, Italy, and **Professor Peter Calverly**, MD, University of Liverpool, UK.

In their two six-month, double-blind, parallel-group studies of patients with moderate-to-severe COPD, over 1500 patients were randomized to receive either the long-acting bronchodilator salmeterol 50 µg twice daily or tiotropium 18mcg once daily, accompanied by one daily dose of either roflumilast 500 µg or a placebo. In the salmeterol- study, 466 patients were treated with roflumilast and 467 with placebo. In the tiotropium-study, 371 patients received roflumilast and 373 a placebo.

The primary outcome, a change in pre-bronchodilator Forced Expiratory Volume in 1 Second (FEV1) from baseline to each post-randomization visit was significantly improved by the combination of the PDA4 inhibitor and the bronchodilator (mean pre FEV1 improved by 49 mL ( $p < 0.0001$ ) with salmeterol and 80mL ( $p < 0.0001$ )with tiotropium.

The mean post-bronchodilator FEV1, a secondary outcome, improved similarly in both studies.

The concomitant regimen also reduced the rate of exacerbations and improved respiratory symptoms in both studies.

The safety profile of the concomitant treatment was consistent with that previously reported for roflumilast. Adverse events occurred in 63.1% of patients receiving roflumilast concomitant with salmeterol bronchodilator treatment compared to 59.1% in patients receiving salmeterol plus placebo. In the combination group tiotropium plus roflumilast, 46% of patients reported side effects as compared to 40% of those receiving tiotropium plus placebo. Diarrhoea, nausea, and weight loss were the most common treatment-related side effects.

“In patients with moderate to severe COPD, roflumiflast improves lung function and disease symptoms, even when concomitantly treated with salmeterol or tiotropium, and thus it could become an important option for these patients. The beneficial effect on lung function is additive to that achieved by bronchodilators. This treatment, however, is not suitable for all patients, because of class-related adverse effects that usually arise soon after initiation of treatment”, concludes Prof. Fabbri.

The ERS is an organization of and for physicians, health professionals, and scientists that advances lung health through programs of education, research, advocacy and practice support that foster excellence in the field of respiratory medicine. For more information, see [www.ersnet.org](http://www.ersnet.org).

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Title: The PDE4 inhibitor roflumilast provides additional clinical benefit in COPD patients receiving salmeterol

Title: Roflumilast, a PDE4 inhibitor, improves lung function in patients with COPD treated with tiotropium

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