



## Atopix Therapeutics announces positive Phase IIb results for once daily OC459 in asthma

**Abingdon UK, March 3<sup>rd</sup> 2014:** Atopix Therapeutics Ltd (“Atopix”), a biopharmaceutical company developing innovative CRTH2 antagonists for allergic disease, announced the results of a Phase IIb asthma study with their lead compound OC459 at the American Academy of Allergy, Asthma and Immunology (AAAAI) Annual Meeting, San Diego, California, USA on March 1st. (Link to poster: <http://www.atopixtherapeutics.co.uk/downloads/atopix-aaaai-poster.pdf>)

CRTH2 is a G protein coupled receptor that is selectively expressed by key cell types mediating allergic responses – Th2 lymphocytes, type 2 innate lymphoid cells, basophils and eosinophils. CRTH2 is activated by prostaglandin D<sub>2</sub>, an abundant lipid product of mast cells.

OC459, a CRTH2 antagonist has previously been shown to reduce airway inflammation and improve lung function in a one month study of allergic asthmatics with moderate persistent disease. The randomized double-blind study was conducted to determine whether OC459 was effective when dosed at 25 mg or 200mg once daily (OD) and 100 mg twice daily (BD) over three months in a study population containing both allergic and non-allergic asthmatics.

Key findings from the study demonstrated that:

- OC459, at a dose of 25mg once a day, showed a statistically significant improvement in lung function compared to placebo.
- The effect was driven by a responder population of patients with a “Th2 high” eosinophilic phenotype. This group benefited from a large statistically significant improvement in lung function, particularly in those patients under 40 years old where the magnitude of improvement was equivalent to that of high-dose inhaled corticosteroids.
- Treatment with OC459 led to a statistically-significant reduction in the incidence of respiratory tract infections, an effect believed to be due to dampening the harmful Th2 immune response detrimental to the outcome of asthma patients infected with rhinovirus. The effect on respiratory tract infection is important because the majority of asthma exacerbations are precipitated by respiratory viral infection.

The most important factor driving response to OC459 was blood eosinophil count, the biomarker test that Atopix Therapeutics is using in current trials in asthma and other allergic indications.

Tim Edwards, Chairman of Atopix, said: “We are delighted that OC459, our leading oral anti-Th2 therapy, had a clinically meaningful impact in eosinophilic asthma. This highlights the need to stratify patients appropriately to define those most likely to derive optimal clinical benefit. There is a pressing need for a safe oral therapy for eosinophilic asthma which has a positive impact on disease progression and risk of exacerbation, as well as simultaneously treating co-morbid allergic diseases such as allergic rhinoconjunctivitis.”

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### About Atopix Therapeutics Ltd

Atopix Therapeutics Limited is a privately held, clinical-stage, biopharmaceutical company based in Oxford, UK, with an innovative approach to allergic disease. The company is developing a novel class of oral anti-allergic medicines, called CRTH2 antagonists, to treat atopic dermatitis, asthma and allergic rhinitis. Its lead candidate is currently being studied in a Phase II clinical trial for moderate-to-severe atopic dermatitis in several leading European dermatology centres. Atopix has a pipeline of highly potent back-up CRTH2 antagonists, including the Phase I ready oral candidate ATX2417, and topical candidates that can be formulated for treatment of a number of severe allergic conditions including eye disease. For more information, please visit <http://www.atopixtherapeutics.co.uk>.

### About Eosinophilic Asthma

Around 40% of asthma patients have eosinophilic disease, most often defined by the presence of eosinophils in induced sputum with associated elevations in blood eosinophil count and exhaled nitric oxide. Patients with eosinophilic asthma tend to have more severe disease, with a proportion having persistent airway eosinophilia despite treatment with high inhaled corticosteroids and remaining at risk of a serious exacerbation requiring hospitalisation.

### About OC459

OC459 is a once-a-day, orally active, CRTH2 antagonist which has been shown to be effective in the treatment of eosinophilic asthma and allergic rhinoconjunctivitis. It provides marked improvements in patients with a Th2 dominant eosinophilic form of disease. Such patients typically have more severe disease and are prone to exacerbations. An attractive feature of OC459 is that it can be used to treat multiple co-morbid allergic diseases simultaneously.