Author's response to reviews

Title: Safety, tolerability, pharmacokinetics and pharmacodynamics of AZD9164, a long-acting inhaled muscarinic antagonist, in healthy volunteers and patients with COPD: analysis of two Phase I, randomised, double-blind, placebo-controlled studies

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Author's response to reviews: see over
Dear Dr Timothy Shipley,

Executive Editor

BMC Pulmonary Medicine

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Re: ‘Safety, tolerability, pharmacokinetics and pharmacodynamics of AZD9164, a long-acting inhaled muscarinic antagonist, in healthy volunteers and patients with COPD: analysis of two Phase I, randomised, double-blind, placebo-controlled studies’

I would like to submit the above manuscript for consideration, review and publication in BMC Pulmonary Medicine. This manuscript is an original work and has been seen and approved by all authors. It is not under consideration by any other journal, in whole or in part.

The current paper presents results from two phase I studies that were conducted to assess the safety and tolerability of multiple ascending doses of AZD9164, an investigational drug with potential as an inhaled long-acting, muscarinic antagonist (LAMA), in healthy white volunteers, healthy Japanese volunteers and patients with COPD. The initial bronchoconstrictor effect observed with AZD9164 in these studies has led to the cessation of all further activities on this molecule. However, we feel that these studies are relevant and will be of interest to your readers as they support the importance of having early timepoint measurements of lung function when evaluating novel inhaled therapies, even when a rapid onset is not expected.

We would like to suggest Professor Roland Buhl and Professor J A Noord (contact details listed at the end of this cover letter) as peer reviewers for this manuscript.

In line with good publication practice, it should be noted these studies were supported by AstraZeneca plc and writing assistance during the development of the manuscript was provided by inScience Communications, also funded by AstraZeneca plc. In terms of conflicts of interest, all of the authors are employees of AstraZeneca. A copy of the study protocol is available on request. I thank you for considering our manuscript for publication and look forward to hearing from you.

Kind regards,

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