

OSELTAMIVIR TREATMENT DOES REDUCE SEVERITY AND DURATION OF INFLUENZA INFECTION

Press Statement

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New analysis of efficacy data confirms that timely administration of the antiviral influenza drug oseltamivir considerably reduces the impact of an influenza infection in adults. The study results have now been published in The Lancet.

The study was conducted by an independent research group led by Arnold Monto, Professor of Epidemiology at the University of Michigan School of Public Health, USA, and Stuart Pocock, Professor of Medical Statistics at the London School of Hygiene and Tropical Medicine. The team had been given access to individual patient data from all the published and unpublished adult treatment trials in seasonal influenza from oseltamivir's manufacturer Roche, hence not only clinical trial study reports, the basis of an earlier meta-analysis on this subject.

A total of nine randomised trials comparing the licensed 75mg twice daily dose of oseltamivir to placebo in 4328 adults were included in the meta-analysis. The trials had similar inclusion criteria, intervention protocol and primary outcome. The primary outcome was defined as time to alleviation of all the following influenza symptoms: nasal congestion, sore throat, cough, aches and pains, fatigue, headaches and chills/sweats. Two of the clinical trials were carried out in elderly

populations and one in individuals with chronic cardiac or respiratory illness.

Analysis of the clinical data clearly showed significant reductions in the duration of influenza virus infection. In patients with proven influenza infection, time to alleviation of all symptoms was shortened by an average of 25.2 hrs (or 21%, from 123 hrs to 98 hrs) and lower respiratory tract complications requiring antibiotics more than 48 hours after study entry were reduced by an estimated 44% (4.9% vs 8.7%) compared with placebo. Concomitantly, the timely use of oseltamivir reduced the number of hospital admissions for any cause by an estimated 63% (0.6% vs 1.7%) in adults with laboratory confirmed-influenza. The only clear side effects attributed to drug therapy were the previously known ones of vomiting (absolute increase 4.7%) and nausea (3.7%).

"Overall we may conclude that oseltamivir has a useful role to play in the treatment of influenza, both seasonal and pandemic." – *Arnold Monto, Department of Epidemiology, University of Michigan School of Public Health, USA.*

The effectiveness of antiviral drugs for influenza has been the subject of scientific debate for many years. The proverbial lack of scientific consensus is an important hurdle to optimizing public health response to outbreaks of (seasonal and pandemic) influenza, and it thus may jeopardize the well-being of patients worldwide. In the aim to resolve this public health issue, a multidisciplinary group of scientific experts had developed an analysis plan for oseltamivir data during the first

Multiparty Group for Advice on Science (MUGAS) meeting on 18 June 2013 in Brussels. The initiative was taken by the MUGAS Foundation, a non-governmental body that aims to promote public health by addressing unsolved scientific issues.

The multidisciplinary group unanimously agreed that reviewing randomised controlled trial data is insufficient to resolve issues regarding efficacy and safety of oseltamivir. Instead, an analysis of the oseltamivir individual patient database is also required to provide further medical evidence of drug effects. This meta-analysis has now provided conclusive evidence of the effectiveness of oseltamivir in adults against seasonal influenza.

"This MUGAS study is of major benefit to society as it will not only help to avoid unnecessary suffering, it will also help to reduce lower respiratory tract complications and hospitalisations." - *Prof. Ab Osterhaus, MUGAS Foundation*

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