



CARDIOVASCULAR NEWS

Arixtra® reduced risk of death or recurrent heart attack

The New England Journal of Medicine (NEJM) and the Journal of the American Medical Association (JAMA) released the results of two large, Canadian-led clinical trials—OASIS 5 and OASIS 6—into a treatment for heart attacks in March 2006.

The OASIS 5 and 6 programs studied over 32,000 patients worldwide. OASIS 6 results are broadly consistent with the large companion study—OASIS 5—conducted in the acute treatment of patients with chest pain (unstable angina)/myocardial infarction (non-ST segment elevation MI).^{1,2} OASIS 5 results were presented last September 2005 at the European Society of Cardiology (ESC).²

OASIS 6

The OASIS 6 (Organization to Assess Strategies for Ischaemic Syndrome) program is an international, randomised, double-blind study assessing the efficacy and safety of Arixtra® (fondaparinux sodium) in patients with STEMI. OASIS 6 evaluated 12,092 patients in 447 sites across 41 countries.³

The purpose of the study was to compare GlaxoSmithKline Inc.'s antithrombotic product Arixtra® to standard therapy in acute coronary syndrome (ACS) patients with ST-elevation MI (STEMI). The overall results of the study demonstrated superiority of fondaparinux to standard therapy (unfractionated heparin or placebo) in reducing the risk of death or recurrent heart attack (risk reduction of 14% at day 30, $p = 0.008$), with a significant reduction observed as early as day nine (risk reduction of 17%, $p = 0.003$). Furthermore, fondaparinux showed a significant reduction in all cause mortality (secondary endpoint) at day nine (risk reduction 13%,

$p = 0.043$), which was maintained until the end of the study (risk reduction 12%, $p = 0.029$).¹

In OASIS 6, the incidence of severe haemorrhage at day nine was similar between fondaparinux and patients treated with standard therapy. In addition, OASIS 6 showed that fondaparinux was associated with a significant net benefit-risk—as assessed by the composite of efficacy and safety endpoints of death, recurrent MI and severe haemorrhage at all time points (at day 30 risk reduction was 14%, $p = 0.005$).¹

“We look forward to submitting these data to regulatory authorities worldwide for review so that we may bring fondaparinux to physicians and patients for use in the treatment of ACS,” said Dr. Lawson Macartney, Senior Vice-President, Cardiovascular and Metabolic Medicine Development Centre, GlaxoSmithKline.

GlaxoSmithKline Inc.

GSK is one of the world's leading research-based pharmaceutical and health-care companies and is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

References

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