

Eisai Europe Limited

Eisai Announce Application to Appeal NICE Judicial Review Verdict

28.09.2007 - 18:10 Uhr, Eisai Europe Limited

London (ots/PRNewswire) - Eisai Limited, the licence holder of Aricept(R) (donepezil hydrochloride) and Pfizer Limited, its co-promotion partner, announced today that Eisai has applied to the Court of Appeal for permission to appeal the recent High Court ruling on the process by which the National Institute for Health and Clinical Excellence (NICE) reached its decision to ban anti dementia medicines for NHS patients with newly diagnosed mild Alzheimer's disease.

Eisai has lodged an application to appeal on the point of procedural fairness based on NICE's repeated refusal to disclose a working version of the cost effectiveness model they used to determine the value of treatment in patients with mild Alzheimer's disease.

Dr Paul Hooper, Managing Director of Eisai Limited said: "We are sad that we are having to take this further action. We maintain our belief that NICE should be required to be fully transparent in the way in which they reach their decisions surrounding the cost effectiveness of medicines."

Notes to Editors

Earlier this year the High Court granted permission to proceed to a Judicial Review on three grounds:

- Procedural: since NICE had repeatedly refused to disclose a fully working version of the cost effectiveness model used to determine the value of treatment in patients with mild Alzheimer's disease, the process leading to the Final Appraisal Determination (FAD) and the new treatment guidance breached the principles of procedural fairness

- Irrationality: some of the assumptions made or conclusions drawn in the FAD are irrational or cannot be supported

- Discrimination: the use of MMSE (Mini Mental State Examination) scores as a rigid diagnostic tool discriminates against certain patient groups

Background

January 2001	NICE approved the use of these medicines by the NHS (donepezil, rivastigmine and galantamine) for the treatment of mild and moderate Alzheimer's disease.
March 2005	NICE first proposed banning NHS prescription of the medicines to newly diagnosed Alzheimer's patients.
July 2005	NICE postponed ratifying the ban but instead asked the manufacturers to supply extra data showing which patients responded best to the medication.
December 2005	NICE considered the data supplied by the manufacturers.
23 January 2006	NICE proposed that moderate AD be treated on the NHS, but not mild. Moderate was defined as starting at 20 on the MMSE scale. A consultation period followed this announcement.
26 June 2006	NICE announced that despite the views of patients and doctors, it planned to stick to its ban on using the treatments for mild AD.
13/14 July 2006	Eisai and Pfizer appealed this decision, along with other manufacturers and organisations including the Alzheimer's

Society and the Royal College of Psychiatrists.

11 October 2006 NICE announced that all grounds of appeal from all parties had been dismissed.

14 November 2006 Eisai and Pfizer called on NICE to:

- withdraw the current FAD and postpone issuing the new guidance
- disclose a fully transparent working version of the calculations used in the cost-effectiveness model for independent evaluation and comment
- develop a new FAD using both a more accurate cost-effectiveness model and data.

22 November 2006 NICE issued new Guidance banning the use of medicines for NHS patients with newly diagnosed mild Alzheimer's disease.

05 January 2007 Eisai and Pfizer confirmed Eisai's application for Judicial Review submission.

23 March 2007 Following consideration of documents lodged, the High Court grants permission to proceed to judicial review on all grounds (procedural fairness, irrationality and discrimination).

25 June 2007 Judicial Review hearing commences at High Court.

10 August 2007 High Court upholds claim of discrimination.

28 September 2007 Eisai and Pfizer announce Eisai's application to the Court of Appeal on the ground of procedural fairness

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 Im Internet recherchierbar: <http://www.presseportal.de>

Contact:
 For further information contact: Andrew Day, Eisai Europe Corporate Affairs Department, +44-(0)208-600-1400, Andrew.Day@Eisai.net

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