THE ROYAL COLLEGE OF OPHTHALMOLOGISTS'

PRESS RELEASE

RCOphth Review concludes that Avastin and Lucentis are equally effective in treating wet AMD

College Review urges NHS Executive to urgently evaluate the use of Avastin in the treatment of AMD

The Royal College of Ophthalmologists has today (Wednesday, 14 December 2011) released the conclusions of a working group of leading experts who reviewed the published scientific literature to assess the efficacy of ranibizumab (Lucentis) and bevacizumab (Avastin) in the treatment of Age Related Macular Degeneration (AMD) [1].

The two drugs are anti-VEGF[2] agents and the working group concluded that both are equally effective in the treatment of AMD and have a similar safety profile.

The use of Avastin instead of Lucentis would save the NHS considerable sums of money but when Avastin is used for the treatment of eye disease it is used "off-label". Current General Medical Council (GMC) guidance states that doctors who prescribe off-label must be satisfied that doing so would *better* serve the patient's needs than using an appropriately licensed alternative. There is no evidence that Avastin is more effective than Lucentis for the treatment of AMD.

The College supports the continued use of Lucentis rather than Avastin for patients with wet AMD who fall within the National Institute for Health and Clinical Excellence (NICE) guidelines for treatment. Primary Care Trusts are legally obliged to fund NHS treatment with Lucentis if an ophthalmologist prescribes it.

The College believes that the NHS executive should **urgently** instruct NICE and the Medicines and Healthcare Products Regulatory Agency (MHRA) to evaluate the use of Avastin in the treatment of AMD and produce National Guidelines for the use of anti-VEGF agents in AMD.

Ophthalmologists should have the discretion to use Avastin rather than Lucentis for the treatment of AMD if it is in the patient's best interest to do so and provided the patient gives informed consent. This may occur, for example, when an ophthalmologist wishes to use an anti-VEGF agent earlier

than specified in the NICE guidelines or when the patient has failed to respond to Lucentis.

The College supports the use of Avastin for medical retina conditions for which no licensed or NICE approved alternative medicine is available.

The ophthalmologist must source the Avastin from a reputable pharmacy.

The key issue is that the patient must be provided with full information about treatment alternatives and must give informed consent.

Notes for Editors

1. Age related macular degeneration (AMD) is one of the commonest causes of visual impairment in the UK and it predominantly affects the elderly. Estimates from the Royal National Institute for the Blind and National Institute of Health and Clinical Excellence indicate there may be 26,000 people with exudative AMD now eligible for treatment in the UK each year. (RCOphth Age-Related Macular Degeneration Guidelines for Management February 2009).

2. There are two forms: geographic atrophy ('dry') AMD that causes very gradual loss of vision and a neovascular ('wet') form of AMD that can cause quite rapid loss of vision. The symptoms of wet AMD occur first in one eye but loss of vision in the second eye may occur sooner or later. The wet form of AMD may be treated by a drug that inhibits the function of a biological growth factor called vascular endothelial growth factor (VEGF) that is a key element in causing the wet form of AMD. Such drugs, termed anti-VEGF agents, are given by injection into the eye and most patients need several injections at regular intervals to get the desired treatment effect. Anti VEGF agents can be very effective in treating wet AMD but not all patients respond to treatment. They arrest progression of AMD and may restore some, but not all, of the sight that has been lost.

3. Ranibizumab (Lucentis) is an anti-VEGF agent that has been specifically developed for treatment of eye conditions and has been shown in clinical trials to be effective in the treatment of 'wet' AMD. It also has a very good safety record. It has been evaluated by the National Institute for Clinical Excellence (NICE) and found to be cost effective. NICE has approved Lucentis for use within the NHS and Primary Care Trusts (PCTs) are legally obliged to fund Lucentis when an ophthalmologist prescribes it for the treatment of AMD. The drug is expensive and costs the NHS £740 per injection. With an average of 7 injections required per eye in the first year of treatment the total cost of the drug per eye can mount to £5,180. For some patients who need treatment over a longer period, the cost of the drug can be considerably more.

4. Bevacizumab (Avastin) is an anti-VEGF agent that was originally developed for the treatment of cancer, where it is given intravenously. It has a similar mode of action to Lucentis. Avastin is licensed for use in cancer treatment and has been used widely around the world for treatment of wet AMD and

other eye disorders. It has not been licensed or approved by NICE for use within the eye. It is not marketed by the manufacturers for treatment of eye disorders or prepackaged in the very much smaller doses required for injection into the eye (specialist pharmacies have been splitting phials of the drug supplied by the manufacturer).
Avastin is much cheaper than Lucentis, costing the NHS about £60 per injection, with a total equivalent cost of £420 in the first year of treatment.

College conflicts of Interest

The College has received financial support from Novartis (the manufacturer of Lucentis) for it educational activities and has in the past received a donations for its research fund. Some College officers and members of Council have received individual support from Novartis and some are employed by Moorfields Eye Hospital whose manufacturing pharmacy markets bevacizumab (Avastin) for ophthalmic use.

The conflicts of interest policy of the College can be viewed at
http://www.rcophth.ac.uk/page.asp?section=383&sectionTitle=College+Policies

More information and advice to the public is available at
www.rcophth.ac.uk

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