(osi) eyetech



March 6, 2006

Dear Health Care Professional,

(OSI) Eyetech Inc. and Pfizer Inc. would like to inform you about important changes in the Macugen® (pegaptanib sodium injection) Prescribing Information concerning reports of **anaphylaxis/anaphylactoid reactions**. The following sections have been amended: CONTRAINDICATIONS, PRECAUTIONS, ADVERSE EVENTS Post-Marketing, and DOSAGE and ADMINISTRATION.

Macugen is indicated for the treatment of neovascular (wet) age-related macular degeneration, and is administered once every six weeks by intravitreous injection. Since market introduction in the United States, there have been rare reports of anaphylaxis/ anaphylactoid reactions, including angioedema, following administration of Macugen along with various medications administered as part of the injection preparation procedure. A direct relationship to pegaptanib or any of the various medications administered as part of the injection preparation procedure or other factors has not been established in these cases. The patient's medical history for hypersensitivity reactions should be evaluated prior to performing the intravitreal injection procedure.

The revisions to the label are as follows with the new information in italics:

CONTRAINDICATIONS

Macugen is contraindicated in patients with ocular or periocular infections.

Macugen is contraindicated in patients with known hypersensitivity to pegaptanib sodium or any other excipient in this product.

PRECAUTIONS

General

FOR OPHTHALMIC INTRAVITREAL INJECTION ONLY.

Rare cases of anaphylaxis/anaphylactoid reactions, including angioedema, have been reported in the post-marketing experience following the Macugen intravitreal administration procedure (see ADVERSE EVENTS and DOSAGE AND ADMINISTRATION).

ADVERSE EVENTS

<u>Post-Marketing Experience:</u> Anaphylaxis/anaphylactoid reactions, including angioedema, have been identified during postapproval use of Macugen. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure (see **PRECAUTIONS and DOSAGE AND ADMINISTRATION**).

DOSAGE AND ADMINISTRATION

The injection procedure should be carried out under controlled aseptic conditions, which includes the use of sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent). The patient's medical history for hypersensitivity reactions should be evaluated prior to performing the intravitreal procedure (see PRECAUTIONS and ADVERSE EVENTS). Adequate anesthesia and a broad-spectrum microbicide should be given prior to the injection.

Healthcare professionals are encouraged to report any serious adverse event information associated with the use of Macugen to Pfizer Inc. at 1-800-438-1985. You can also report the information directly to the FDA via the MedWatch system at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail (using a postage-paid form) or the internet at www.fda.gov/medwatch.

Attached is the revised prescribing information for Macugen®. If you would like further information, please contact the Pfizer Medical Drug Information Department at 1-800-438-1985.

Sincerely,

Anthony P. Adamis, MD Chief Scientific Officer

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(OSI) Eyetech, Inc.

Michael Widlitz MD Vice President, US Medical

Pfizer Inc.