

# Genentech

IN BUSINESS FOR LIFE

1 DNA Way  
South San Francisco, CA 94080-4990  
(650) 225-1000  
FAX: (650) 225-6000

January 24, 2007

Dear Health Care Provider:

Genentech would like to inform you of important safety information regarding LUCENTIS® (ranibizumab injection). In an ongoing study (SAILOR) of ranibizumab delivered intravitreally to patients with neovascular (wet) age-related macular degeneration (AMD), a planned interim safety analysis of Cohort 1 showed a higher incidence of strokes in the 0.5-mg dose group compared with the 0.3-mg dose group (1.2% versus 0.3%, respectively;  $P=0.02$ ). Patients with a history of prior stroke appeared to be at higher risk for a subsequent stroke. For the arterial thromboembolic events of myocardial infarction or vascular death, the differences between the doses were not statistically significant. The overall safety of intravitreal injections of ranibizumab (0.3-mg and 0.5-mg doses) appears to be consistent with the safety experience from Phase III studies as described in the LUCENTIS® (ranibizumab injection) prescribing information.

The objectives of the SAILOR study are to evaluate the safety of 2 doses (0.3 mg versus 0.5 mg) of ranibizumab (Cohort 1), and to monitor safety and provide access to LUCENTIS® (0.5 mg only) for patients (Cohort 2) during the pre-approval period earlier in 2006. Serious adverse events (SAEs) are being continuously monitored in SAILOR and the planned interim safety analysis was performed on data from Cohort 1 patients with an average follow-up of 230 days.

We look forward to analyzing all of the safety data in the later half of 2007 when the SAILOR study is completed.

If you have any questions regarding the use of LUCENTIS®, please call our Medical Information/Communication Department at 1-800-821-8590.

Health care professionals should report any serious adverse events suspected to be associated with the use of LUCENTIS® to Genentech at 1-888-835-2555. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178), online (<https://www.accessdata.fda.gov/scripts/medwatch/>), or mailed, using the MedWatch Voluntary Reporting Form 3500, to the FDA Safety Information and Adverse Event Reporting Program, Food and Drug Administration, 5600 Fishers Ln, Rockville, MD 20852-9787.

Sincerely,



Hal Barron, MD  
Senior Vice President, Development  
Chief Medical Officer  
Genentech, Inc.