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Genentech, Inc. Submits Biologics License Application For FDA Review Of Lucentis(TM) In Wet Age-Related Macular Degeneration

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SOUTH SAN FRANCISCO, Calif., Dec. 30 /PRNewswire-FirstCall/ -- Genentech, Inc. announced today that it has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the use of Lucentis(TM) (ranibizumab) in the treatment of neovascular wet age-related macular degeneration (AMD). Lucentis is the first therapy for wet AMD to have shown improved vision in two pivotal Phase III trials and demonstrated a clinical benefit over verteporfin (Visudyne(R)) photodynamic therapy (PDT) in a head-to-head clinical trial. As part of the Lucentis BLA submission, Genentech has requested a Priority Review designation from the FDA, which, if granted, would give the FDA six months from the

Agency's receipt of the submission to take action on the application.

The BLA submission is based on one-year clinical data on the efficacy and safety of Lucentis from two pivotal Phase III trials, ANCHOR and MARINA, as well as one-year clinical data from the Phase I/II FOCUS trial. In addition to these registrational studies, Genentech is currently enrolling patients with wet AMD in a Phase IIIb safety study called SAILOR. Data from the Phase IIIb PIER study evaluating a less frequent dosing regimen for Lucentis are anticipated in the first half of 2006.

"This application represents a summary of data from more than six years of rigorous clinical study and the dedication of thousands of patients and physicians hoping to improve outcomes for those with this devastating disease," said Hal Barron, M.D., Genentech's senior vice president of Development and chief medical officer. "We look forward to working with the FDA in our efforts to bring this potential therapy to patients quickly as it may offer benefit to patients with all types of wet AMD."

ANCHOR

In November 2005, Genentech announced positive preliminary data from the pivotal

Phase III ANCHOR study (ANti-VEGF Antibody for the Treatment of Predominantly Classic CHORoidal Neovascularization in AMD), a randomized, two-year, multi-center, double-masked, active-treatment controlled study comparing two different doses of Lucentis to PDT in 423 patients with predominantly classic wet AMD. Approximately 94 percent of patients treated with 0.3 mg of Lucentis and 96 percent of those treated with 0.5 mg of Lucentis maintained (defined as a loss of less than 15 letters in visual acuity) or improved vision (defined as a gain of 15 letters or more) compared to approximately 64 percent of those treated with PDT alone [p<0.0001] during the first year of the two-year study. The Lucentis treatment groups further showed a statistically significant difference from the control arm in an important secondary endpoint: mean change in visual acuity (VA) from baseline to month 12. On average, VA among patients treated with Lucentis improved, while VA among patients treated with PDT declined. Based on these results, patients in the PDT-alone arm of the study will have access to Lucentis for the remainder of the study. One-year data from the ANCHOR study will be presented at the Macula 2006 meeting in New York in January.

MARINA

In July 2005, Genentech presented positive preliminary one-year results from the pivotal Phase III MARINA study (Minimally classic/occult trial of the Anti-VEGF antibody Ranibizumab In the treatment of Neovascular AMD), a randomized, two-year, multi-center, double-masked, sham-injection controlled study evaluating the safety and efficacy of two different doses of Lucentis in 716 patients with minimally classic or occult wet AMD. Nearly 95 percent of patients treated with Lucentis maintained or improved vision at 12 months. Additional one-year results include:

-- Twenty five percent (59/238) of patients treated with 0.3 mg of Lucentis and 34 percent (81/240) treated with 0.5 mg of Lucentis improved vision by a gain of 15 letters or more compared to approximately 5 percent (11/238) of patients in the control group as measured by the ETDRS eye chart. -- Nearly 40 percent (188/478) of Lucentis-treated patients (38.7 percent in the 0.3 mg group and 40 percent in the 0.5 mg group) achieved a visual acuity score of 20/40 or better compared to 11 percent (26/238) in the control group. -- Patients treated with Lucentis gained an average of approximately seven letters in visual acuity (6.5 letters in the 0.3 mg group and 7.2 letters in the 0.5 mg group) compared to study entry, while those in the control group lost an

patients treated with Lucentis (349/478) (74.8 percent in the 0.3 mg group and 71.3 percent in the 0.5 mg group) experienced a letter improvement of zero or more compared to 28.6 percent (68/238) in the sham group.

In October 2005, Genentech announced that patients still in the sham arm of the MARINA study would be crossed over to active treatment with Lucentis.

FOCUS

The FOCUS trial (RhuFab V2 Ocular Treatment Combining the Use of Visudyne(R) to Evaluate Safety) is a randomized, two-year, multi-center, single-masked study evaluating the safety, tolerability and efficacy of Lucentis in combination with PDT compared to PDT alone in 162 patients with predominantly classic subfoveal wet AMD. Preliminary one-year data were presented in July 2005 and showed that approximately 90 percent of patients maintained or improved vision when treated with the combination of Lucentis and PDT compared to approximately 68 percent of those treated with PDT alone (p = 0.0003).

Lucentis Safety Profile

In clinical trials to date, the most common side effects that occurred more frequently in the Lucentis arms (0.3 mg and 0.5 mg) than in the

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