

Ophthotech Announces Results from Pivotal Phase 3 Trials of Fovista® in Wet Age-Related Macular Degeneration

- | *No benefit observed upon addition of Fovista® to monthly Lucentis® regimen for the treatment of wet age-related macular degeneration -*
- | *Conference Call and Webcast Today, December 12, 2016 at 8:30 a.m. ET -*

NEW YORK--(BUSINESS WIRE)-- Ophthotech Corporation (Nasdaq:OPHT) today announced that the pre-specified primary endpoint of mean change in visual acuity at 12 months was not achieved in its two pivotal Phase 3 clinical trials investigating the superiority of Fovista® (pegpleranib) anti-PDGF therapy in combination with Lucentis® (ranibizumab) anti-VEGF therapy compared to Lucentis® monotherapy for the treatment of wet age-related macular degeneration (AMD). The addition of Fovista® to a monthly Lucentis® regimen did not result in benefit as measured by the mean change in visual acuity at the 12 month time point.

"We are very disappointed in the results from these trials, particularly for patients afflicted with wet AMD," commented David R. Guyer, M.D., Chief Executive Officer of Ophthotech. "We are thankful to the patients and clinical investigators and their staff for participating in the trials. We will continue to analyze the data from these two studies to better understand the trial results."

The two clinical trials (OPH1002 and OPH1003) were international, multicenter, randomized, double-masked, controlled Phase 3 studies evaluating the safety and efficacy of 1.5 mg of Fovista® administered in combination with Lucentis® (Fovista® combination therapy) compared to Lucentis® monotherapy. In each of these trials, patients were randomized to one of two approximately equal sized treatment groups. The two Phase 3 trials enrolled an aggregate of 1,248 patients with wet AMD. The results from the databases of the two trials were unmasked and analyzed concurrently.

The combined analysis from the two trials (OPH1002 and OPH1003) showed that patients receiving Fovista® combination therapy gained a mean of 10.24 letters of vision on the Early Treatment of Diabetic Retinopathy Study (ETDRS) standardized chart at 12 months, compared to a mean gain of 10.01 ETDRS letters for patients receiving Lucentis® monotherapy, a difference of 0.23 ETDRS letters. In OPH1002, consisting of 619 treated patients, subjects receiving Fovista® combination therapy gained a mean of 10.74 letters of vision on the ETDRS standardized chart at 12 months, compared to a mean gain of 9.82 ETDRS letters in patients receiving Lucentis® monotherapy, a resulting difference of 0.92 ETDRS letters ($p=0.44$). In OPH1003, consisting of 626 treated patients, subjects receiving Fovista® combination therapy gained a mean of 9.91 letters of vision on the ETDRS standardized chart at 12 months, compared to a mean gain of 10.36 ETDRS letters in patients receiving Lucentis® monotherapy, a resulting difference of -0.44 ETDRS letters ($p=0.71$). None of these results of the pre-specified primary efficacy analysis were statistically significant.

In the pooled analysis of pre-specified secondary endpoints from both trials, 24.2% of patients receiving Fovista® combination therapy gained 20 or more ETDRS letters from baseline at month 12, compared to 22.1% of patients receiving Lucentis® monotherapy. In OPH1002, 25.9% of patients receiving Fovista® combination therapy gained 20 or more ETDRS letters from baseline at month 12, compared to 20.0% of patients receiving Lucentis® monotherapy. In OPH1003, 22.5% of patients receiving Fovista® combination therapy gained 20 or more ETDRS letters from baseline at month 12, compared to 24.1% of patients receiving Lucentis® monotherapy.

In the pooled analysis, 12.1% of patients receiving Fovista® combination therapy lost 5 or more ETDRS letters from baseline at month 12, compared to 11.2% of patients receiving Lucentis® monotherapy. In OPH1002, 12.0% of patients receiving Fovista® combination therapy lost 5 or more ETDRS letters at month 12, compared to 12.3% of patients receiving Lucentis® monotherapy. In OPH1003, 12.2% of patients receiving Fovista® combination therapy lost 5 or more ETDRS letters at month 12, compared to 10.2% of patients receiving Lucentis® monotherapy.

In addition, in the pooled analysis, 13.5% of patients receiving Fovista[®] combination therapy achieved visual acuity of 20/25 or better at month 12, compared to 13.9% of patients receiving Lucentis[®] monotherapy. In OPH1002, 13.6% of patients receiving Fovista[®] combination therapy achieved visual acuity of 20/25 or better, compared to 13.2% of patients receiving Lucentis[®] monotherapy. In OPH1003, 13.5% of patients receiving Fovista[®] combination therapy achieved visual acuity of 20/25 or better, compared to 14.6% of patients receiving Lucentis[®] monotherapy.

Based on a preliminary analysis of the safety data from these two trials, Fovista[®] combination therapy and Lucentis[®] monotherapy were generally well tolerated after one year of treatment. The ocular adverse events more frequently reported in the Fovista[®] combination therapy group compared to the Lucentis[®] monotherapy group were mainly related to the injection procedure. The incidence of reported serious systemic adverse events was generally similar in both treatment groups as was the incidence of myocardial infarction or cerebrovascular accident.

Conference Call Information

Ophthotech's management team will host a live conference call and webcast today at 8:30 a.m. Eastern Time to discuss the data. To participate in the conference call, dial 877-675-4749 (USA Toll Free) or 719-325-4781 (International Toll), passcode 4199836. A live, listen-only audio webcast of the conference call can be accessed on the Investor Relations section of the Ophthotech website, www.opthotech.com. A replay will be available approximately two hours following the live call, and will be accessible for two weeks. The replay number is 888-203-1112 (USA Toll Free), passcode 4199836. The audio webcast can be accessed at: www.opthotech.com.

About Ophthotech Corporation

Ophthotech is a biopharmaceutical company specializing in the development of novel therapeutics to treat back of the eye diseases, with a focus on developing innovative therapies for age-related macular degeneration (AMD). Ophthotech's most advanced product candidate, Fovista[®] anti-PDGF therapy, is in Phase 3 clinical trials for use in combination with anti-VEGF therapy that represents the current standard of care for the treatment of wet AMD. Ophthotech's second product candidate, Zimura[®], an inhibitor of complement factor C5, is being developed for the treatment of geographic atrophy, a form of dry AMD, and in combination with anti-VEGF therapy in wet AMD patients. For more information, please visit www.opthotech.com.

Forward-looking Statements

Any statements in this press release about Ophthotech's future expectations, plans and prospects constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about Ophthotech's strategy, future operations and future expectations and plans and prospects for Ophthotech, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "goal," "may," "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. In this press release, Ophthotech's forward looking statements include statements about the timing, progress and results of the Fovista[®] Phase 3 clinical program. Such forward-looking statements involve substantial risks and uncertainties that could cause Ophthotech's clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the initiation and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory approvals or other actions and other factors discussed in the "Risk Factors" section contained in the quarterly and annual reports that Ophthotech files with the Securities and Exchange Commission. Any forward-looking statements represent Ophthotech's views only as of the date of this press release. Ophthotech anticipates that subsequent events and developments will cause its views to change. While Ophthotech may elect to update these forward-looking statements at some point in the future, Ophthotech specifically disclaims any obligation to do so except as required by law.

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