

# Ophthotech Announces Fovista® Phase 2b Independent Analysis Shows that Fovista® Anti-PDGF Therapy, Combined with Anti-VEGF Therapy, is Associated with a Reduction of Sub-retinal Fibrosis in Wet AMD Patients

- Presentation Will Occur at the 2014 American Academy of Ophthalmology Annual Meeting -

NEW YORK--(BUSINESS WIRE)-- Ophthotech Corporation (Nasdaq:OPHT) today announced that a subgroup analysis assessing the development and progression of sub-retinal fibrosis in the Company's Phase 2b trial comparing Fovista<sup>®</sup> (1.5mg) combination therapy with Lucentis<sup>®</sup> (0.5mg) versus Lucentis<sup>®</sup> (0.5mg) monotherapy will be presented at the American Academy of Ophthalmology 2014 Annual Meeting in Chicago, Illinois. Sub-retinal fibrosis is a major cause of visual loss in wet age-related macular degeneration (AMD) patients treated with the current standard of care, anti-VEGF monotherapy, according to third party studies<sup>1</sup>.

This analysis will be presented on Tuesday, October 21, 2014 from 11:26 - 11:33 a.m. Central Daylight Time (CDT):

 Abstract PA092: "Dual Antagonism of Platelet Derived Growth Factor (Fovista<sup>®</sup> 1.5 mg) and Vascular Endothelial Growth Factor (Lucentis<sup>®</sup> 0.5 mg) Results in Reduced Sub-retinal Fibrosis and Neovascular Growth," Authors: Dr. U. Chakravarthy and Dr. G.J. Jaffe.

The abstract summarizing the analysis is published on the AAO website: https://secure.aao.org/apps/.

#### **Highlights of the Abstract**

The purpose of the retrospective analysis was to assess the evolution and severity of sub-retinal fibrosis in eyes with visual loss (n=70) treated with either the combination  $Fovista^{(B)}$  (1.5 mg) and  $Fovista^{(B)}$  (0.5 mg) or monotherapy  $Fovista^{(B)}$  (0.5 mg). Certified and independent readers masked to drug and treatment regimen assessed the evolution and/or progression of fibrosis. Retinal images were graded on a 0 to 4 categorical scale of increasing severity of sub-retinal fibrosis.

The mean change in severity of sub-retinal fibrosis from baseline to the conclusion of the study at 24 weeks was 0.97 vs. 2.0 (P = 0.003), favoring the Fovista<sup>®</sup> (1.5mg) combination therapy group. At 24 weeks, approximately twice the number of patients on standard of care anti-VEGF monotherapy (54%) were noted to have progression of sub-retinal fibrosis compared to the Fovista<sup>®</sup> (1.5mg) combination therapy group (27%). In eyes without any sub-retinal fibrosis at baseline, sub-retinal fibrosis developed in 10% of patients receiving Fovista<sup>®</sup> (1.5mg) combination therapy group compared to 51% in the monotherapy Lucentis<sup>®</sup> group.

"We are very pleased that the American Academy of Ophthalmology has accepted this abstract and recognized the importance of this independent analysis from our Phase 2b study of Fovista<sup>®</sup> combination therapy for wet AMD patients," stated David R. Guyer, M.D., Chief Executive Officer and Chairman of the Board of Ophthotech. "The occurrence of sub-retinal fibrosis is considered to be the best clinical predictor of poor visual outcome in wet AMD treated patients. Thus, we believe that the potential for inhibiting formation or progression of sub-retinal fibrosis with Fovista<sup>®</sup> combination therapy holds great promise for treating an unmet medical need for wet AMD patients. We are currently enrolling patients in the initial trial of our anti-fibrosis program to confirm these findings."

#### **About Sub-retinal Fibrosis**

Sub-retinal fibrosis is a pathological process in the evolution of wet AMD. The formation of fibrosis disrupts the retina and its architecture, which leads to irreversible visual loss. A large (1059 patients) National Eye Institute funded CATT Research Group Study showed that evolution of sub-retinal fibrosis was common in patients with wet AMD treated with monotherapy anti-VEGF therapy. Approximately 32% of patients at one year and 45% of patients at two years developed sub-retinal fibrosis in this CATT trial<sup>1</sup>.

## About the Fovista® Phase 3 Program

Ophthotech's Fovista<sup>®</sup> Phase 3 program consists of three clinical trials to evaluate the safety and efficacy of Fovista<sup>®</sup> (anti-PDGF) therapy in combination with anti-VEGF drugs for the treatment of wet age-related macular degeneration (AMD). The Company expects to enroll approximately 1,866 patients in more than 225 centers worldwide. Initial topline data from the Fovista<sup>®</sup> Phase 3 clinical program are expected to be available in 2016.

#### **About Wet AMD**

Age-related macular degeneration is a disease characterized by progressive degenerative abnormalities in the macula of the eye, a small area in the central portion of the retina. Age-related macular degeneration (AMD) is classified into one of two general subgroups: the "dry" (non-neovascular) and the "wet" (exudative or neovascular) form of the disease. The "dry" form of AMD is characterized by a slow degeneration of the macula resulting in atrophy of the central retina, with gradual vision loss over a period of years. The "wet" form of AMD typically causes sudden, often substantial, loss of central vision and is responsible for most cases of severe loss of visual acuity in this disease. AMD is characteristically a disease of individuals aged 50 years or older, and is the leading cause of blindness in developed countries around the world in this age group.

#### **About Ophthotech Corporation**

Ophthotech is a biopharmaceutical company specializing in the development of novel therapeutics to treat diseases of the eye, with a focus on developing innovative therapies for age-related macular degeneration (AMD). Ophthotech's most advanced product candidate, Fovista<sup>®</sup> anti-PDGF therapy, is in Phase 3 clinical trials for use in combination with anti-VEGF drugs that represent the current standard of care for the treatment of wet AMD. Ophthotech's second product candidate, Zimura<sup>TM</sup>, an inhibitor of complement factor C5, is being developed for the treatment of geographic atrophy (a form of dry AMD) and in combination with Fovista<sup>®</sup> and anti-VEGF therapy for wet AMD. For more information, please visit www.ophthotech.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. Forwardlooking statements include any statements about Ophthotech's strategy, future operations and future expectations and plans and prospects for Ophthotech and its product candidates, 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 potential of Fovista as a wet AMD combination therapy, the potential anti-fibrotic effect of Fovista combination therapy and the initiation of additional clinical trials for Fovista and obtaining data from these additional planned trials. 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 express or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the initiation and conduct of clinical trials, and the availability of data from clinical trials and other factors discussed in the "Risk Factors" section contained in the quarterly and annual reports that Ophthotech files with the SEC. 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.

<sup>1</sup> Daniel, E; Toth, CA; Grunwald, JE; Jaffe, GJ; Martin, DF; Fine, SL; Huang, J; Ying, G-S; Hagstrom, SA; Winter, K; Maguire, MG. Risk of scar in the comparison of Age-related Macular Degeneration Treatments Trials. *Ophthalmology*. 2010; 121:656-666.

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