Ohr Pharmaceutical Announces Positive Results of a Phase II Clinical Study for OHR-102 in Retinal Vein Occlusion

OHR-102 Combination Therapy Enhances Visual Recovery in Macular Edema Secondary to Retinal Vein Occlusion

NEW YORK, July 13, 2015 (GLOBE NEWSWIRE) -- Ohr Pharmaceutical, Inc. (Nasdaq:OHRP), an ophthalmology research and development company, today announced positive final results from a Phase II investigator sponsored clinical trial of OHR-102 (0.2% Squalamine lactate ophthalmic solution) in patients with macular edema secondary to branch (BRVO) and central retinal vein occlusion (CRVO). The results demonstrated that, following an initial 10 week combination therapy treatment period, patients who continued to receive a combination of topical OHR-102 BID plus Lucentis® achieved greater visual acuity gains than the control group who received Lucentis alone. At week 38, the mean gain in visual acuity from baseline for patients randomized (at week 10) to treatment with OHR-102 + Lucentis PRN was +27.8 letters compared with +23.3 for patients randomized to treatment with Lucentis plus PRN alone (control group), a clinically meaningful difference of +4.5 letters. The data were presented by John Wroblewski, MD, a retina specialist at Cumberland Valley Retina Consultants on Saturday, July 11 at the 2015 Annual Meeting of the American Society of Retina Specialists (ASRS) in Vienna, Austria.

"These very promising final results demonstrate a clinically meaningful treatment effect of OHR-102 combination therapy for the treatment of macular edema secondary to retinal vein occlusion," said John Wroblewski, MD, principal investigator of this Phase II study. "The 38 week data confirm a positive and meaningful effect on both visual acuity and macular edema. Importantly, continued treatment with OHR-102 combination therapy for the full 38 weeks of the study resulted in further improvements in visual gains over those patients that only received combination therapy for the first 10 weeks of the study."

This investigator-sponsored trial was designed to determine the effect of OHR-102 in eyes with macular edema secondary to retinal vein occlusion. The data presented at ASRS included the final analysis of patients that, following a 10 week initial combination treatment period, were randomized to receive either continued OHR-102 + Lucentis PRN therapy or only Lucentis monotherapy PRN through week 38. After the initial combination therapy phase, the mean gain in visual acuity from week 10 to week 38 was +7.4 letters for patients who continued treatment with OHR-102 + Lucentis PRN compared with +3.1
letters in those receiving Lucentis PRN alone. Furthermore, at week 38, 80% of patients in the OHR-102 + Lucentis treated group had a gain in visual acuity, compared with 50% of patients treated with Lucentis alone. Additionally, at week 38, none of the patients in the OHR-102 + Lucentis treated group lost any vision. Patients treated with OHR-102 + Lucentis PRN required a mean of 2.0 Lucentis injections between weeks 10 and 38, compared with a mean of 3.3 Lucentis injections for the monotherapy group over the same time period.

"The positive results of this Phase II study demonstrates the role of OHR-102 combination therapy in RVO and represent an important milestone for the development of OHR-102 in the treatment of this disease," said Dr. Jason Slakter, Chief Medical Officer of Ohr. "This trial constitutes the second clinical study in a retinal vascular disorder which has shown a positive and clinically meaningful benefit in visual acuity using OHR-102 combination therapy versus an intravitreal anti-VEGF injection alone. The consistency of the efficacy data in this study, combined with the favorable safety profile of OHR-102, we believe warrants further study in a large controlled clinical trial."

Study Design

The 38 week, investigator sponsored, Phase II clinical trial enrolled 20 treatment naïve patients with macular edema due to retinal vein occlusion. All patients received OHR-102 topically for the first 10 weeks of treatment, with two injections of Lucentis given at week 2 and week 6. The week 10 results were presented at ASRS 2014, and demonstrated that the combination of topical OHR-102 eye drops and intravitreal Lucentis led to a mean gain in visual acuity of 20.3 letters and resolution of the foveal edema in 95% of the patients. In the extension stage of the study (weeks 10 to 38), patients were randomized 1:1 at week 10 to either continue administering OHR-102 eye drops or discontinue drops for the remainder of the study. Retreatment with Lucentis injections were administered monthly as needed (PRN) through week 38 based on OCT criteria.

About Ohr Pharmaceutical, Inc.

Ohr Pharmaceutical, Inc. is an ophthalmology research and development company whose lead product, Squalamine, is being studied as an eye drop formulation (OHR-102) in several company-sponsored and investigator sponsored Phase II clinical trials for various back-of-the-eye diseases. These diseases include wet-AMD, retinal vein occlusion, and proliferative diabetic retinopathy. In addition, Ohr has a sustained release micro fabricated micro-particle ocular drug delivery platform with several preclinical drug product candidates in development for glaucoma, steroid-induced glaucoma, ocular allergies, and protein drug delivery. Additional information on the company may be found at www.ohrpharmaceutical.com.

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