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Ohr Pharmaceutical Presents Data From OHR-102 Phase II IMPACT Study in Wet-AMD at ARVO Conference

- *Visual Acuity Benefits Demonstrated in Classic CNV Containing Lesions*
- *Data Support a Phase III Development Program in an Optimized Wet-AMD Patient Population*

NEW YORK, May 7, 2015 (GLOBE NEWSWIRE) -- Ohr Pharmaceutical, Inc. (Nasdaq:OHRP), an ophthalmology research and development company, presented the results from the Phase II IMPACT study evaluating OHR-102 (0.2% Squalamine lactate ophthalmic solution) combination therapy for the treatment of the wet form of age-related macular degeneration (wet-AMD) at the Association for Research in Vision and Ophthalmology (ARVO) conference, in Denver, CO. The data were presented by Dr. Jason Slakter, Ohr's Chief Medical Officer and retina specialist at Vitreous-Retina-Macula Consultants of New York.

Data presented included the analysis of visual acuity outcomes for patients completing the nine month treatment period (modified intent-to-treat or mITT population). In the mITT population with lesions containing classic choroidal neovascularization (classic containing lesions) (OHR-102 n=37, Lucentis® monotherapy n=28), mean gains in visual acuity at month nine were +11 letters for the OHR-102 combination arm and +5 letters with Lucentis monotherapy, a clinically meaningful benefit of 6 letters. In addition, 44% of the patients receiving OHR-102 combination therapy achieved a ≥3 line vision gain at nine months, as compared to 29% in the Lucentis monotherapy group. This positive effect on visual acuity in classic containing lesions was observed early in the course of treatment and continued to increase through the end of the study. The classic containing CNV population represents approximately two thirds of the total wet-AMD patient population.

The mITT data in classic containing lesions also showed a more pronounced separation between the OHR-102 and Lucentis monotherapy groups for those patients who achieved ≥4 and ≥5 line vision gains. Of the patients receiving OHR-102, 22% achieved a ≥4 line gain and 14% achieved ≥5 gains, at nine months, as compared to 7% with a ≥4 line gain and 7% with a ≥5 line gain for those who received Lucentis monotherapy. The mITT overall population, comprising the patients with either classic containing or occult only lesions, (OHR-102 n=65, Lucentis monotherapy n=63), demonstrated a lesser benefit, with patients gaining +7.8 letters for the OHR-102 combination arm and +5.3 letters for Lucentis monotherapy.

"The results from the IMPACT study demonstrate that topically administered OHR-102 combination therapy can lead to improved visual function in patients with wet AMD and, importantly, that the efficacy results may be determined by lesion size and composition," stated Dr. Jason Slakter, Chief Medical Officer at Ohr. "There was a clear and clinically meaningful benefit in patients whose lesions contained some classic CNV. These data support a Phase III development program in a targeted population which will be based upon a complete analysis of the IMPACT study results. We expect to commence the Phase III development program with OHR-102 combination therapy in the second half of 2015."

Dr. Slakter also presented the data on patients with classic containing lesions in the intent-to-treat (ITT-LOCF) population (OHR-102 n=38, Lucentis monotherapy n=32). In this group, the mean gains in visual acuity were +10.5 letters for the OHR-102 combination arm and +5.4 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.1 letters. In addition, 42% of the patients receiving OHR-102 achieved a ≥3 line gain at nine months, as compared to 28% in the Lucentis monotherapy group.

As previously reported, the mean number of injections between the treatment arms over the 9 months of treatment, the primary endpoint of the study, was not meaningfully different.

IMPACT Study Design

The IMPACT study was a nine-month Phase II clinical trial evaluating the safety and efficacy of OHR-102 for the treatment of wet-AMD. The two treatment arms were OHR-102 drops administered twice daily plus Lucentis PRN ("OHR-102" arm or group) versus placebo eye drops administered twice daily plus Lucentis PRN ("Lucentis monotherapy" arm or group). All patients in the study received an initial Lucentis injection. 142 patients were randomized into the study, with 90% of the patients completing the nine month treatment protocol. OHR-102 was generally well tolerated, with only two treatment related discontinuations in the study.

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, diabetic macular edema, 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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This news release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are made only as the date thereof, and Ohr Pharmaceutical

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