Ohr Pharmaceutical Announces New Positive Anatomic and Visual Acuity Data on OHR-102 (Squalamine Eye Drops) IMPACT Study Presented at the 2014 American Academy of Ophthalmology Scientific Meeting

Reduction of Subretinal Hyperreflective Material (SHRM) Induced by OHR-102 Correlates With Improved Vision Outcomes

Regression of the SHRM Biomarker in Wet-AMD and Vision Improvement is Consistent With Mechanism of Action of OHR-102

NEW YORK, Oct. 20, 2014 (GLOBE NEWSWIRE) -- Ohr Pharmaceutical, Inc. (Nasdaq:OHRP), an ophthalmology research and development company, announced today that additional positive clinical data from the IMPACT study were presented at the 2014 American Academy of Ophthalmology (AAO) Annual Scientific Meeting, in Chicago, Illinois. The IMPACT study is a nine month phase II clinical trial evaluating Squalamine Eye Drops (OHR-102) for the treatment of the wet form of age-related macular degeneration (wet AMD). The data, presented in the AAO late breaker session by Dr. David S. Boyer on Saturday, October 18, demonstrated that the combination of OHR-102 plus Lucentis® resulted in a marked improvement in subretinal hyperreflective material (SHRM), an anatomical biomarker for wet-AMD. The regression of SHRM observed was greater in the OHR-102 combination arm compared to the Lucentis monotherapy arm. A clear relationship was demonstrated between this reduction in the SHRM biomarker and the improvements in visual acuity seen in the study. In addition, the IMPACT study demonstrated that the OHR-102 combination arm had a greater proportion of patients with total resolution of SHRM compared to the Lucentis monotherapy arm.

"The interim data from the IMPACT study show that the combination of OHR-102 eye drops and Lucentis leads to better visual and anatomical outcomes in a broad wet AMD patient population," said Dr. David S. Boyer of Retina-Vitreous Associates Medical Group, Beverly Hills, and a clinical investigator in the IMPACT study. "The improvements we observed in retinal anatomy, as measured by quantitative analysis of SHRM, are important as they provide an explanation for the dramatic early and sustained visual gains achieved in these patients."
The quantitative analysis of the SHRM biomarker was conducted at a large independent reading center in the U.S. Two masked readers reviewed and measured the area of SHRM on the spectral domain optical coherence tomography (OCT) scans at baseline and the final visit. Only patients with measurable SHRM at baseline were included in the analysis (overall: OHR-102 arm n=27, Lucentis monotherapy n=27, Classic containing lesions: OHR-102 n=18, Lucentis monotherapy n=13). SHRM, which is visualized using OCT, is an important biomarker of neovascular AMD and is believed to represent a combination of neovascular tissue, pre-fibrotic material and other subretinal exudative and inflammatory debris.

In the IMPACT study overall population, patients receiving OHR-102 combination therapy demonstrated a 75% mean reduction in the area of SHRM as compared to 56% in the Lucentis monotherapy group. In addition, 59% of patients in the OHR-102 combination arm achieved a complete resolution of SHRM versus 44% in the monotherapy arm. The mean reduction in SHRM directly correlated with the visual acuity improvements seen in each vision outcome category, with a greater reduction of SHRM in each consecutive vision gain category up to more than 90% reduction of SHRM in patients achieving ≥4 lines (≥20 letters) of visual acuity gains.

"The correlation demonstrating a relationship between reduction in SHRM and increased vision outcomes are potentially groundbreaking and provide us with additional insight into the etiology of this complex neovascular disease," said Dr. Peter Kaiser, Retina Specialist at the Cole Eye Institute and Senior Vice President of Product Development at Ohr. "The increased vision improvement seen in patients with better SHRM reduction is likely caused by the normalization of retinal architecture, restoration of contact between the retinal pigment epithelium and photoreceptors, and decreased development of fibrosis. This is a good example of how multi-factor blockade in age related macular degeneration leads to disease modification not seen with anti-VEGF alone."

Given that previous combination therapy trials in wet AMD focused on classic containing lesions, and SHRM is seen more often in classic choroidal neovascularization (CNV), a subgroup analysis was performed on this patient population. In these patients, even more pronounced differences in SHRM reductions were observed. Patients receiving OHR-102 combination therapy demonstrated a 74% mean reduction in the area of SHRM as compared to 43% in the Lucentis monotherapy group. In addition, 56% of patients in the OHR-102 combination arm achieved a complete resolution of SHRM versus 31% in the monotherapy arm. As with the overall analysis, the mean reduction in SHRM in these patients directly correlated with the visual acuity improvements seen in each vision outcome category, with a greater reduction of SHRM in each consecutive vision gain category up to more than 90% reduction of SHRM in patients achieving ≥4 lines (≥20 letters) of visual acuity gains.

The OHR-102 patients with classic CNV also saw an improvement in visual function, with 61% of patients achieving a 20/40 vision outcome and 39% achieving a 20/32 outcome as compared to 40% and 20%, respectively, in the Lucentis monotherapy group. These levels of visual acuity represent important thresholds of visual function including the ability to perform daily tasks such as, drive a car, or read without magnification.
In addition to this anatomic data, Dr. Thomas Ciulla presented important data on the IMPACT study. The two podium presentations from the AAO meeting will be available on the investor relations page of Ohr’s website.

**About Squalamine Eye Drops (OHR-102)**

Squalamine is an anti-angiogenic small molecule with a novel intracellular mechanism of action, which counteracts multiple growth factors and pathways implicated in the angiogenic process, including vascular endothelial growth factor (VEGF), platelet-derived growth factor (PDGF), and basic fibroblast growth factor (bFGF). Ohr Pharmaceutical has developed a novel eye drop formulation of Squalamine (OHR-102) for the treatment of wet AMD, designed for convenient, patient self-administration, which may provide clinical utility for this patient population and other back-of-the-eye disorders. In May 2012, the Squalamine eye drop program was granted Fast Track Designation by the FDA. Interim Phase II data from the ongoing IMPACT study has demonstrated benefit in visual function versus placebo across multiple standard parameters. Three additional investigator sponsored trials are evaluating Squalamine eye drops for the treatment of proliferative diabetic retinopathy, retinal vein occlusion, and diabetic macular edema, and two Phase III studies in wet AMD are expected to be initiated in the first half of calendar 2015.

**About Ohr Pharmaceutical, Inc.**

Ohr Pharmaceutical, Inc. (OHRP) is an ophthalmology research and development company. The company’s lead product, Squalamine, is currently being studied as an eye drop formulation in several company sponsored and investigator sponsored Phase II clinical trials for various back-of-the-eye diseases, including the wet form of age-related macular degeneration, 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. The lead sustained release program in glaucoma is proceeding under a collaboration with a large global pharmaceutical company. Additional information on the company may be found at [www.ohrpharmaceutical.com](http://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 undertakes no obligation to update or revise the forward-looking statement whether as a result of new information, future events or otherwise. Our actual results may differ materially and adversely from those expressed in any forward-looking statements as a result of various factors and uncertainties, including the future success of our scientific studies, our ability to successfully develop products, rapid technological change in our markets, changes in demand for our future products, legislative, regulatory and competitive developments, the financial resources available to us, and general economic conditions. Shareholders and prospective investors are cautioned that no assurance of the efficacy of pharmaceutical products can be claimed or assured until final testing; and no assurance or warranty can be made that the FDA or Health Canada will approve final
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