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# **Ohr Pharmaceutical Announces Additional Squalamine Eye Drop (OHR- 102) Phase II Clinical Data in Wet-AMD; The IMPACT Study**

## **Data Presented at the 2014 Annual Meeting of the American Society of Retina Specialists**

NEW YORK, Aug. 13, 2014 (GLOBE NEWSWIRE) -- Ohr Pharmaceutical, Inc. (Nasdaq:OHRP), an ophthalmology research and development company, today announced additional interim data from the Phase II study evaluating Squalamine Eye Drops (OHR-102) for the treatment of the wet form of age-related macular degeneration ("wet-AMD"). The data demonstrated a visual acuity and anatomical benefit for the group of patients receiving the combination of OHR-102 and Lucentis® PRN ("OHR-102 arm") versus placebo eye drops plus Lucentis PRN ("Lucentis monotherapy arm"). Jason Slakter, MD, retina specialist and Chief Medical Officer at Ohr, presented the data on Tuesday, August 12 at the 2014 Annual Meeting of the American Society of Retina Specialists ("ASRS").

### **Study 002 Interim Analysis; The IMPACT Study**

This planned interim analysis was conducted on the first 62 patients (29 treated in the Squalamine (OHR-102) arm, 33 treated in the Lucentis monotherapy arm), who completed the entire nine months of the treatment protocol (representing approximately 50 percent of the targeted study population). All patients in the study received an initial Lucentis injection followed by Lucentis as needed (PRN) based on clinical response. The two treatment arms were Squalamine eye drops (OHR-102) administered twice daily plus Lucentis PRN (OHR-102 arm) versus the standard of care Lucentis monotherapy arm. Ohr previously announced data from this trial on June 24<sup>th</sup>.

The OHR-102 treated group demonstrated improved best-corrected visual acuity (BCVA) gains relative to the Lucentis monotherapy group at all timepoints evaluated from four to 38 weeks. In the interim analysis group, 48.3 percent of OHR-102 treated patients showed BCVA gains of  $\geq 15$  letters ( $\geq 3$  lines) on a standard ETDRS eye-chart, compared with 21.2 percent in the monotherapy arm at the end of the study ( $p=0.025$ ). In addition, patients receiving OHR-102 drops were more than twice as likely to gain  $\geq 4$  and  $\geq 5$  lines of vision compared with patients in the Lucentis monotherapy arm ( $\geq 4$  lines  $p=0.022$ ,  $\geq 5$  lines

p=0.059). Mean gain in visual acuity was +10.4 letters in the OHR-102 arm vs. +6.3 letters in the Lucentis monotherapy arm (p=0.18). Importantly, the visual acuity gains for the Lucentis monotherapy arm were consistent with those observed in previous clinical studies using Lucentis monotherapy treatment.

New data presented at ASRS showed that mean change in central subfield thickness was -139 $\mu$ m in the OHR-102 arm versus -117 $\mu$ m in the Lucentis monotherapy arm. Representative cases were shown at ASRS demonstrating that the combination of OHR-102 and Lucentis resulted in the resolution of sub-retinal hyper reflective material as well as intra-retinal and subretinal edema.

"The enhanced vision gains of OHR-102 in combination with Lucentis over the Lucentis monotherapy regimen are encouraging," said Dr. Jeffrey Heier, Director of the Vitreoretinal Service at Ophthalmic Consultants of Boston, member of Ohr's scientific advisory board, and study investigator. "Visual acuity is the primary concern of our patients, and to be able to potentially augment their visual function with a non-invasive option would be of great benefit to them."

There were no significant differences in the frequency of Lucentis PRN injections, which was the primary endpoint of the exploratory Phase II study. As announced previously, the mean number of Lucentis injections was 6.2 for the OHR-102 arm and 6.4 for the Lucentis monotherapy arm, which included the baseline injection and any injections required up to and including the final study visit for the interim analysis group. Squalamine (OHR-102) eye drops were well tolerated and had a comparable safety profile to Lucentis monotherapy arm.

Given that previous combination therapy trials have focused on classic lesions, a subgroup analysis was performed on this patient population. In the group of patients with a lesion containing a classic component and a size of up to 12 disc areas, 67 percent of OHR-102 treated patients (n=18) demonstrated BCVA gains of  $\geq 3$  lines on a standard ETDRS eye-chart, compared with 20 percent in the Lucentis monotherapy arm (n=15) at the end of the study (p=0.007). In addition, patients receiving OHR-102 drops were more than three times as likely to gain  $\geq 4$  and  $\geq 5$  lines of vision compared with patients in the Lucentis monotherapy arm ( $\geq 4$  lines p=0.05,  $\geq 5$  lines p=0.12). Mean change in visual acuity was +13.8 letters in the OHR-102 arm as compared to +6.7 letters in the Lucentis monotherapy arm (p=0.15).

The full slide deck from the ASRS presentation is posted on the Company's website [www.ohrpharmaceutical.com](http://www.ohrpharmaceutical.com).

### ***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, platelet-derived growth factor, and basic fibroblast growth factor. Ohr Pharmaceutical has developed a novel eye drop formulation of Squalamine (OHR-102) for the treatment of retinal neovascular diseases, designed for convenient, patient self-administration, which may provide clinical utility for back-of-the-eye disorders. In May 2012, the Squalamine eye drop program was

granted Fast Track Designation by the U.S. Food and Drug Administration (FDA). A Phase II randomized, double masked, placebo-controlled study (Study-002; the IMPACT Study) to evaluate the efficacy and safety of Squalamine eye drops for the treatment of wet AMD is ongoing and has completed enrollment. Interim data released in June 2014 demonstrated benefit in visual function versus monotherapy 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.

### ***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 is developing 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).

### ***Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995:***

*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 testing or marketing of any pharmaceutical product. Ohr's most recent Annual Report and subsequent Quarterly Reports discuss some of the important risk factors that may affect our business, results of operations and financial condition. We disclaim any intent to revise or update publicly any forward-looking statements for any reason.*

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