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Ohr Pharmaceutical Announces Squalamine Eye Drop (OHR-102) Phase II Clinical Data in Retinal Vein Occlusion

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

NEW YORK, Aug. 11, 2014 (GLOBE NEWSWIRE) -- Ohr Pharmaceutical, Inc. (Nasdaq:OHRP), an ophthalmology research and development company, today announced data supporting the use of Squalamine Eye Drops (OHR-102) in the treatment of macular edema secondary to branch (BRVO) or central retinal vein occlusion (CRVO). The data demonstrated that the combination of topical Squalamine eye drops and intravitreal Lucentis® led to a mean gain in visual acuity ("VA") of 20.3 letters and resolution of the foveal edema in 95% of the patients at week 10. John Wroblewski, MD, retina specialist at Cumberland Valley Retina Consultants, presented the 10 week data on Saturday, August 9 at the 2014 Annual Meeting of the American Society of Retina Specialists.

"I am encouraged by the data using a combination approach with Squalamine to treat retinal vein occlusions," said John Wroblewski, MD, principal investigator of this study. "The early effect on visual acuity, edema, and percentage of early responders appears to be better than those seen in historical monthly Lucentis retinal vein occlusion trials. I look forward to the completion of the extension stage of the study and presenting those results in the first quarter of 2015."

This investigator-sponsored trial was designed to determine the effect of Squalamine Eye Drops (OHR-102) in eyes with macular edema secondary to retinal vein occlusion. 20 treatment naïve patients with macular edema due to retinal vein occlusion were enrolled: nine with non-ischemic CRVO, eight with BRVO and three with hemi-central RVO. All 20 patients received OHR-102 for the first ten weeks of treatment, with two injections of Lucentis given at week 2 and week 6. At week 10, the average EDTRS letter gain was +18.2 for CRVO, +18.1 for BRVO, and +32.3 for HRVO. In addition, 80% of patients achieved gains of ≥ 3 lines in visual acuity, with 40% of patients achieving gains of ≥ 4 lines in VA. Overall, mean Snellen visual acuity at week 10 was 20/32 for all groups and there was a mean improvement in central foveal thickness on optical coherence tomography (OCT) from 723 to 270 microns. Only one patient out of the 20 required an injection of Lucentis at week 10 using predefined OCT based rescue criteria. In the extension stage of the study, patients were randomized 1:1 at week 10 to either continue Squalamine Eye

Drops (OHR-102) twice a day or discontinue drops for the remainder of the 38-week study. Lucentis could be administered based on OCT-based retreatment criteria.

Study Design (Study 004)

The study is an investigator sponsored, single site, prospective clinical trial. In the study, all 20 patients received Squalamine Eye Drops (OHR-102) for the first ten weeks of treatment, with two injections of Lucentis given at week 2 and week 6. In the extension stage of the study, patients were randomized 1:1 at week 10 to either continue administering Squalamine Eye Drops (OHR-102) or discontinue drops for the remainder of the 38-week study. Rescue injections of Lucentis will be administered as needed through week 38 based on OCT criteria. Laser photocoagulation was not permitted during the study. The primary and secondary endpoints include visual acuity parameters, need for rescue retreatments, retinal thickness, vascular leakage and change in area of non-perfusion.

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 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.

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.

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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CONTACT: CORPORATE CONTACT:

Ohr Pharmaceutical Inc.
Investor Relations
888-388-2327
ir@ohrpharmaceutical.com

LifeSci Advisors, LLC
Michael Rice
646-597-6979
mrice@lifesciadvisors.com

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