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# **Ohr Pharmaceutical Announces Positive Animal Studies for Novel Squalamine Eye Drop for Wet-AMD**

## **Studies Confirm Ocular Safety and Therapeutic Concentrations in the Back of the Eye**

NEW YORK, NY -- (MARKET WIRE) -- 07/13/11 -- Ohr Pharmaceutical (OTCBB: OHRP) today announced positive results from two critical animal studies on the recently announced Squalamine eye drop formulation for the treatment of wet-age related macular degeneration ("wet-AMD"). The data from the two animal studies indicate that the novel eye drop formulation is safe when applied to the eye, and furthermore it enters the tissues in the back of the eye in concentrations known to block choroidal neovascularization ("CNV").

In a dose escalation safety study involving daily eye drop treatment in Dutch belted rabbits over a 28 day period, the formulation proved safe, and exhibited no signs of ocular toxicity or changes in intraocular pressure. Importantly, no macroscopic or histopathological changes to the ocular tissues were noted.

In a separate drug bio-distribution study, a single eye drop was administered to the front of the eye in Dutch belted rabbits. At all evaluated timepoints, drug concentrations in the posterior sclera-choroid region behind the retina at the back of the eye far exceeded the tissue concentrations of Squalamine that are known to block the deleterious CNV process in wet-AMD. The study results also demonstrated that the drug was undetectable in the anterior chamber of the eye (aqueous humor), confirming that it does not penetrate through all the layers of the cornea or contact the lens. Topical treatment eliminates the major discomforts and serious complications of the current standard of care, Lucentis®, which include endophthalmitis (severe vision threatening infection) and retinal detachment.

"As a retina surgeon, I am excited by the data which demonstrates strong potential ability to treat wet-AMD with an eye drop," commented Michael J. Elman M.D., founder of the Elman Retina Group in Baltimore, Maryland and Assistant Professor of Ophthalmology at the Johns Hopkins University School of Medicine. "Besides the considerable convenience to the patient, avoiding repeated intravitreal injections will remove the associated risks of ocular inflammation, retinal detachment and sight threatening infection."

Thomas A. Ciulla M.D., retina specialist at The Midwest Eye Institute in Indianapolis, Indiana commented, "The retina community eagerly looks forward to a less frequent and

less invasive treatment regimen. Topical treatment, either as monotherapy or as adjunctive therapy to decrease the frequency of visits and intravitreal injections, will represent a significant step in the right direction for treatment of exudative age-related macular degeneration."

Squalamine was previously used in Phase I and Phase II clinical trials as an intravenous infusion where it had shown a good safety profile and efficacy in treating wet-AMD. However, there was a steep decline in drug concentrations between consecutive dosings to therapeutically ineffective levels for extended periods of time, as confirmed by pharmacokinetic analysis. The eye drop formulation provides a solution to this by allowing the patient to consistently self administer and replenish the dose level required to maintain therapeutically effective concentrations without the expensive need for physician administration of intraocular injections and its attendant risks.

"These new data solidify the value of our eye drop program and the path forward to clinical efficacy trials for the treatment of wet-AMD with this patient friendly mode of administration," stated Irach B. Taraporewala Ph.D., CEO of Ohr Pharmaceutical Inc. "We are very excited about the Squalamine program and its immense potential to create a paradigm shift in the multi-billion dollar wet-AMD market."

#### About Squalamine

Squalamine is a small molecule anti-angiogenic with a novel intracellular mechanism of action, that counteracts not only Vascular Endothelial Growth Factor ("VEGF") but also other angiogenic growth factors such as Platelet Derived Growth Factor ("PDGF"). Recent clinical evidence has shown PDGF to be an additional key target for the treatment of wet-AMD. Using the intravenous formulation in over 250 patients in Phase 1 and Phase 2 trials for the treatment of wet-AMD, Squalamine demonstrated good safety and efficacy in both early and advanced wet-AMD. The previous IV formulation had been awarded fast track status and a Special Protocol Assessment for a phase III registration study from the U.S. Food and Drug Administration ("FDA").

#### About Wet Age Related Macular Degeneration

Wet-AMD is a medical condition which usually affects older adults and generally results in a loss of vision. AMD occurs in "dry" and "wet" forms. Wet-AMD is the advanced form of macular degeneration that robs the elderly of their eyesight, and involves the formation of abnormal and leaky blood vessels in the back of the eye behind the retina, through a process known as choroidal neovascularization ("CNV"). The wet form accounts for approximately 15 percent of all AMD, yet is responsible for 90 percent of severe vision loss associated with AMD. According to the National Eye Institute (NEI), the prevalence of wet-AMD among adults 40 years or older in the U.S. alone is estimated at 1.75 million people. In addition, more than 200,000 new cases are diagnosed yearly in the U.S.

#### About Ohr Pharmaceutical Inc.

Ohr Pharmaceutical Inc. (OTCBB: OHRP) ([www.ohrpharmaceutical.com](http://www.ohrpharmaceutical.com)) is a publicly traded pharmaceutical development company dedicated to the clinical development of new drugs for underserved therapeutic needs in large and growing markets. The company is focused on two lead compounds: Topical Squalamine eye drops for the treatment of the wet form of age-related macular degeneration, and OHR/AVR118 for the treatment of

cancer cachexia, currently being investigated in a Phase II trial.

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

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