NEW YORK, Jan. 05, 2018 (GLOBE NEWSWIRE) -- Ohr Pharmaceutical, Inc. (NASDAQ:OHRP), a clinical-stage pharmaceutical company developing novel therapies for ophthalmic diseases, today reported topline data from the MAKO study which did not meet its primary efficacy endpoint. The MAKO study evaluated the efficacy and safety of topically administered squalamine in combination with monthly Lucentis® injections for the treatment of wet age-related macular degeneration (“wet-AMD”). The primary efficacy endpoint was the mean visual acuity gain at nine months, using a mixed-effects model for repeated measures (MMRM) analysis. Subjects receiving squalamine combination therapy (n=119) achieved a mean gain of 8.33 letters from baseline versus 10.58 letters from baseline with Lucentis® monotherapy (n=118). There were no differences in the safety profile between the two treatment groups.

“We are very disappointed with the outcome of the MAKO study,” commented Dr. Jason Slakter, chief executive officer of Ohr. “We are grateful to the patients and physicians who participated in the clinical trial. Based on these results, we intend to evaluate strategic alternatives to maximize shareholder value.”

About the MAKO Study
The MAKO study was a multi-center, randomized, double-masked, placebo-controlled clinical trial to evaluate the efficacy and safety of squalamine combination therapy for the treatment of wet-AMD. Subjects were randomized 1:1 to receive topical squalamine lactate ophthalmic solution, 0.2%, (“squalamine”) twice daily (“BID”) and monthly Lucentis® injections (“squalamine combination”) or topical placebo BID and monthly Lucentis® injections (“Lucentis monotherapy”). Eligibility criteria for the study eye included: newly diagnosed with wet-AMD and no previous treatment, occult neovascularization, if present, measured less than 10mm² as assessed by fluorescein angiography, and visual acuity between 20/40 and 20/320. A total of 237 subjects were randomized. Visual acuity was measured monthly using the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. The primary efficacy endpoint was the mean visual acuity gain at nine months, using a mixed-effects model for repeated measures (MMRM) analysis.

About Ohr Pharmaceutical, Inc.
Ohr Pharmaceutical, Inc. (OHRP) is a clinical-stage pharmaceutical company developing novel therapies for ophthalmic diseases. The company has completed two clinical trials.
with squalamine lactate ophthalmic solution, 0.2%, for the treatment of the wet form of age-related macular degeneration. In addition, Ohr has a sustained-release micro-fabricated micro-particle ocular drug delivery platform technology.

**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 we undertake 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 our ability to raise sufficient funds to perform and conclude clinical trials, the financial resources available to us, the ability to negotiate and conclude a strategic partnership, 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, 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 will approve final testing or marketing of any pharmaceutical product. Our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q discuss some of the important risk factors that may affect our business, results of operations and financial condition.

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