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Ohr Pharmaceutical, Inc. Announces Enrollment of First Patient in Phase III Wet AMD Clinical Program

NEW YORK, April 18, 2016 (GLOBE NEWSWIRE) -- Ohr Pharmaceutical, Inc. (NASDAQ:OHRP), a clinical-stage biotechnology company developing novel therapies for ophthalmic diseases, today announced that the first patient has been enrolled in the first Phase III clinical trial of its lead drug candidate squalamine lactate ophthalmic solution, 0.2% ("Squalamine", also known as OHR-102), for the treatment of neovascular age-related macular degeneration (wet AMD).

"The Phase III clinical program will examine the potential of Squalamine, when administered as part of a combination therapy, to significantly improve visual acuity in patients with wet AMD," said Dr. Jason Slakter, CEO of Ohr. "We are focused on successfully executing the trials in an expeditious manner. The Phase III program is designed to provide the data required for regulatory approval in major ophthalmic markets worldwide."

The first of two randomized, double-masked, placebo-controlled trials will include approximately 165 centers in the United States and Canada with a target enrollment of 650 treatment naïve subjects with wet AMD. In March 2016, Ohr reached an agreement on a Special Protocol Assessment (SPA) with the U.S Food and Drug Administration (FDA).

Phase III Clinical Program Design:

The comprehensive Phase III clinical program will be comprised of double-masked, placebo-controlled, multicenter, international studies of squalamine lactate ophthalmic solution, 0.2%, ("Squalamine", also known as OHR-102) administered twice a day in subjects with newly diagnosed wet AMD, in combination with Lucentis[®] injections. The primary endpoint will be a measurement of visual acuity gains at nine months, with subjects followed to two years for safety. The eligibility criteria will include subjects with choroidal neovascularization (CNV) secondary to AMD. The lesions in these subjects may contain classic and/or occult CNV, provided the occult CNV component of these lesions measures less than 10mm² as assessed on fluorescein angiography. More information can be found on www.clinicaltrials.gov (NCT02727881).

About Ohr Pharmaceutical, Inc.

Ohr Pharmaceutical, Inc. (Nasdaq:OHRP) is an ophthalmology research and development

company. The company's lead drug candidate, squalamine lactate ophthalmic solution, 0.2% ("Squalamine", also known as OHR-102), is currently being evaluated in a phase III clinical program 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 with several preclinical drug product candidates in development for glaucoma, steroid-induced glaucoma, ocular allergies, and protein drug delivery. 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 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 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 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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