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Ohr Pharmaceutical, Inc. Announces SPA Agreement with US FDA and Initiation of Phase III Wet AMD Clinical Program

First of Two Planned Phase III Trials Initiated to Evaluate Squalamine (OHR-102) Combination Therapy for the Treatment of Wet AMD

NEW YORK, March 29, 2016 (GLOBE NEWSWIRE) -- Ohr Pharmaceutical, Inc. (NASDAQ:OHRP), a clinical-stage biotechnology company developing novel therapies for ophthalmic diseases, today announced that it has reached an agreement on the Special Protocol Assessment (SPA) with the United States Food and Drug Administration (US FDA) on the design of the Phase III trial for its lead drug candidate, squalamine lactate ophthalmic solution, 0.2% ("Squalamine," also known as OHR-102). Based on the agreed upon SPA, Ohr has initiated the first of two planned Phase III global clinical studies evaluating the efficacy and safety of Squalamine, given in combination with Lucentis®, for the treatment of neovascular age-related macular degeneration (wet AMD).

"We are extremely pleased to have completed the SPA process. This agreement with the FDA enables us to move forward with the Squalamine Phase III clinical program," commented Dr. Jason Slakter, CEO of Ohr. "The initiation of our Phase III clinical program is a monumental achievement for the company and represents an important step in our mission to develop and commercialize therapeutics for unmet medical needs in ophthalmology."

"This is fantastic news for the retinal community and the patients in our care," said Dr. David S. Boyer, retina specialist at Retina-Vitreous Associates Medical Group, Beverly Hills, CA, and a member of Ohr's Scientific Advisory Board. "Based on my clinical experience, Squalamine is a promising drug with the potential to non-invasively improve visual function over the current standard of care. I look forward to the opportunity to enroll patients in this important clinical study."

Dr. Avner Ingerman, Ohr's Chief Clinical Officer, added, "We are working with the retinal community and Ohr's Scientific Advisory Board to expeditiously implement a high-quality Phase III clinical development program to fully support future regulatory applications."

The first of two randomized, double-masked, placebo-controlled trials will include approximately 165 centers in the United States and Canada and is expected to enroll approximately 650 treatment naïve subjects with wet AMD. The primary efficacy endpoint of the clinical trial is the change in visual function at nine months.

About a Special Protocol Assessment (SPA)

A Special Protocol Assessment (SPA) from the FDA is a special procedure by which the FDA provides official evaluation and written agreement that the design and planned analysis of a study adequately address the objectives necessary to support a regulatory submission. More information about the FDA's Special Protocol Assessment process is available at <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm080571.pdf>

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. The occult CNV component of these lesions must measure less than 10mm² as assessed on fluorescein angiography.

About Ohr Pharmaceutical, Inc.

Ohr Pharmaceutical, Inc. (NasdaqCM: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 studied as an eye drop formulation in clinical trials for back-of-the-eye diseases, including 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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