
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 24, 2014

Ohr Pharmaceutical, Inc.
(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other Jurisdiction of Incorporation)	<u>333-88480</u> (Commission File Number)	<u>#46-5622433</u> (IRS Employer Identification No.)
<u>800 Third Avenue, 11th Floor, New York, NY</u> (Address of Principal Executive Offices)		<u>10022</u> (Zip Code)

Registrant's telephone number, including area code: (212)-682-8452

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01. Regulation FD.

On June 24, 2014, at 8:30 a.m. (Eastern Time), Ohr Pharmaceutical, Inc. (the “Company”) held a live teleconference call and webcast to provide additional information on the interim clinical trial results of a Phase II clinical trial of Squalamine eye drops in patients with wet age-related macular degeneration. As a supplement to the teleconference call and webcast, the Company provided a slide presentation, a copy of which is attached to this Current Report on Form 8-K as exhibit 99.1. The slide presentation will also be available at www.ohrpharmaceutical.com.

The information contained herein is being furnished pursuant to Item 7.01 of Form 8-K, “Regulation FD Disclosure.” This information shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On June 24, 2014, the Company issued a press release announcing interim results of a Phase II clinical trial of Squalamine eye drops in patients with wet age-related macular degeneration. A copy of the press release is being furnished as exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

Number	Description
Exhibit 99.1	Slide deck for Ohr Pharmaceutical, Inc. teleconference call and webcast presentation on June 24, 2014.
Exhibit 99.2	Press release dated June 24, 2014

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OHR PHARMACEUTICAL, INC.

By: /s/ Irach Taraporewala
Dr. Irach Taraporewala, President and CEO
Date: June 24, 2014



Squalamine Eye Drops
Phase II Interim Data
Wet-AMD Trial

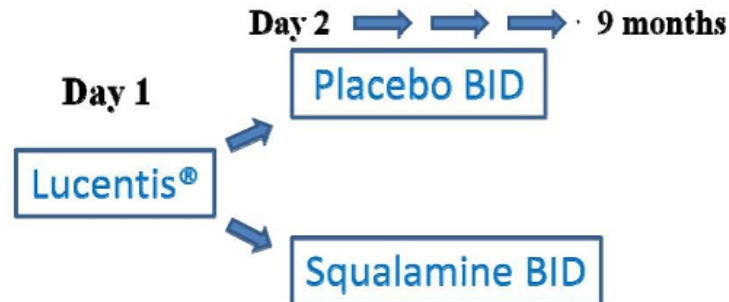
June 24, 2014



Safe Harbor Statement

This presentation 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 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. For example, there can be no assurance that Ohr will be able to sustain operations for expected periods. 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. 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.

Study Design



- Treatment naïve patients with wet AMD
 - All lesion compositions (Classic and occult only lesions allowed)
 - Lesion size ≤ 12 disk areas in size
 - Visual acuity 20/40 to 20/320
- Diabetic patients eligible for study
- Monthly assessment visits
 - Evaluated for Lucentis retreatment using strict PRN criteria based on current standard of care
- Enrollment completed in April 2014 (total = 142 patients)

Lucentis is a registered trademark of Genentech, Inc.



Interim Analysis

- Pre-specified, quantitative, interim analysis when ~50% of patients complete the study protocol
 - 62 patients completed 9 month treatment period and are included in this interim database lock
 - Squalamine eye drops + Lucentis PRN* (29 patients)
 - Placebo eye drops + Lucentis PRN* (33 patients)
 - Pre-specified safety and efficacy parameters analyzed
 - No pre-planned efficacy or futility rules

*Lucentis PRN Regimen- As needed injections determined at each visit using strict standard of care retreatment criteria



Baseline Demographics

Feature	Mean	Range
Baseline Visual Acuity	59.8 letters	30-78 letters
OCT CRT	414.6 microns	298-769 microns
FA Lesion Size	8.5 sq mm	0.29 - 31.1 sq mm
FA CNV Size	8.3 sq mm	0.29 - 31.1 sq mm

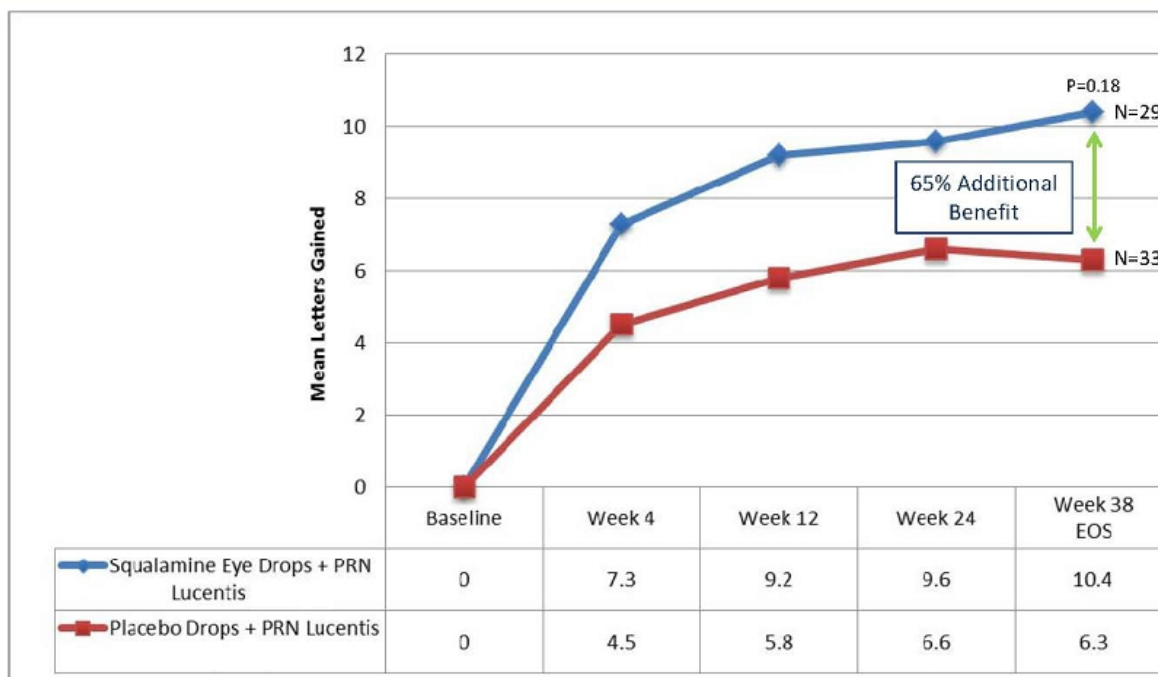


Baseline Demographics

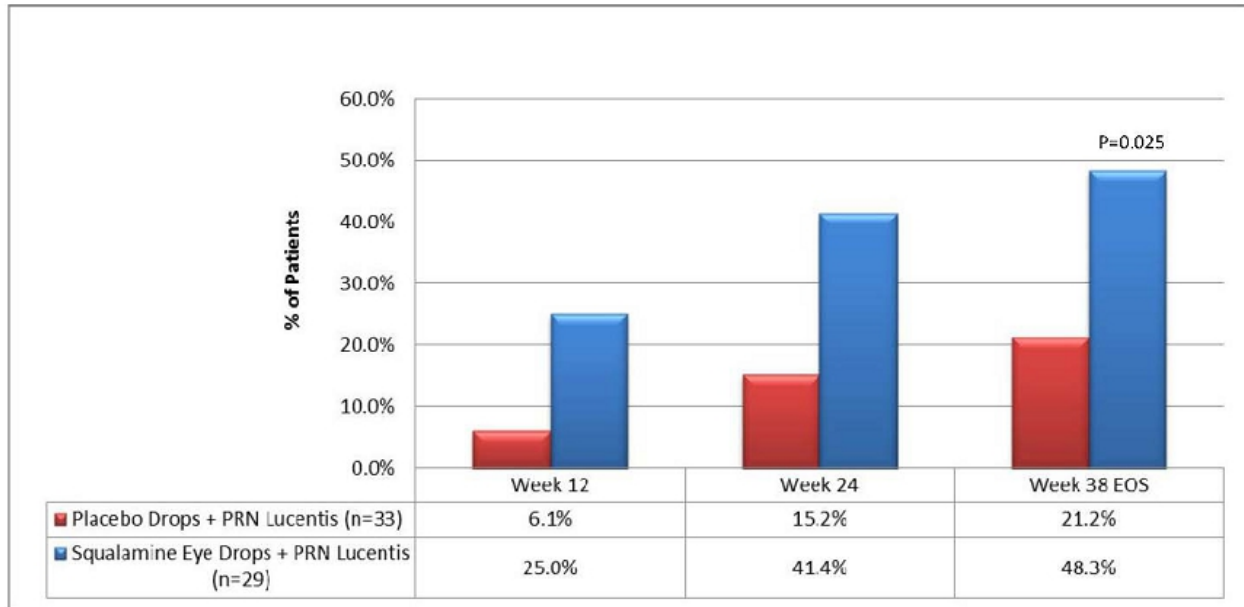
FA Lesion Type	N	Percentage
Predominantly Classic	12	19.4%
Minimally Classic	21	33.8%
Occult Only	29	46.8%



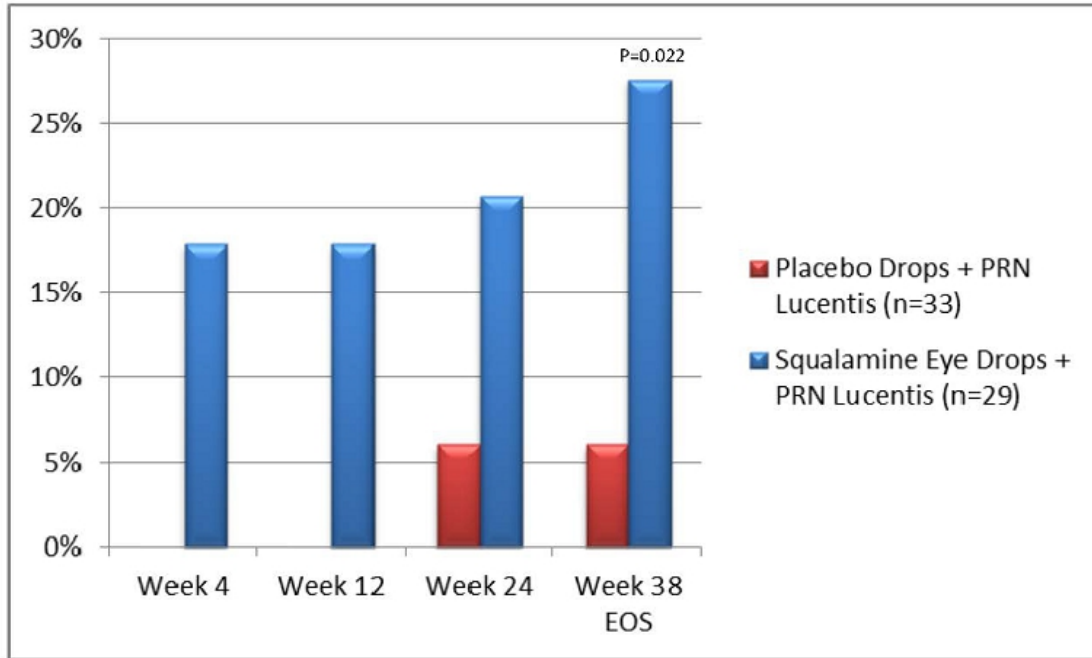
Mean Change in Visual Acuity



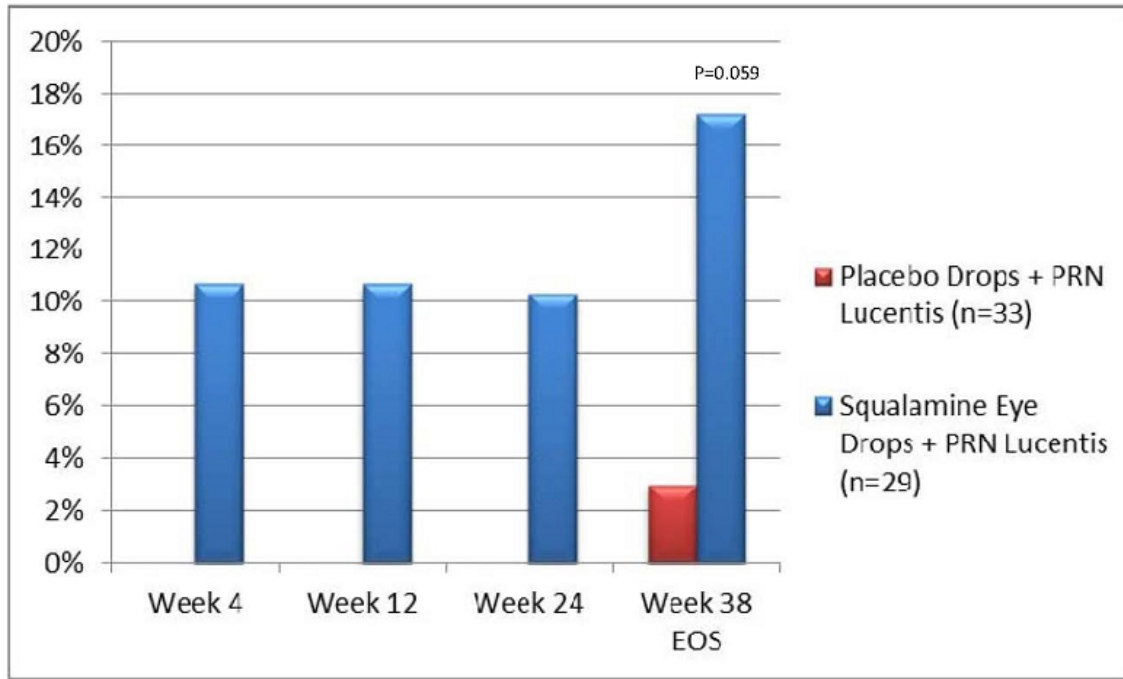
Percentage ≥ 3 Line VA Gainers



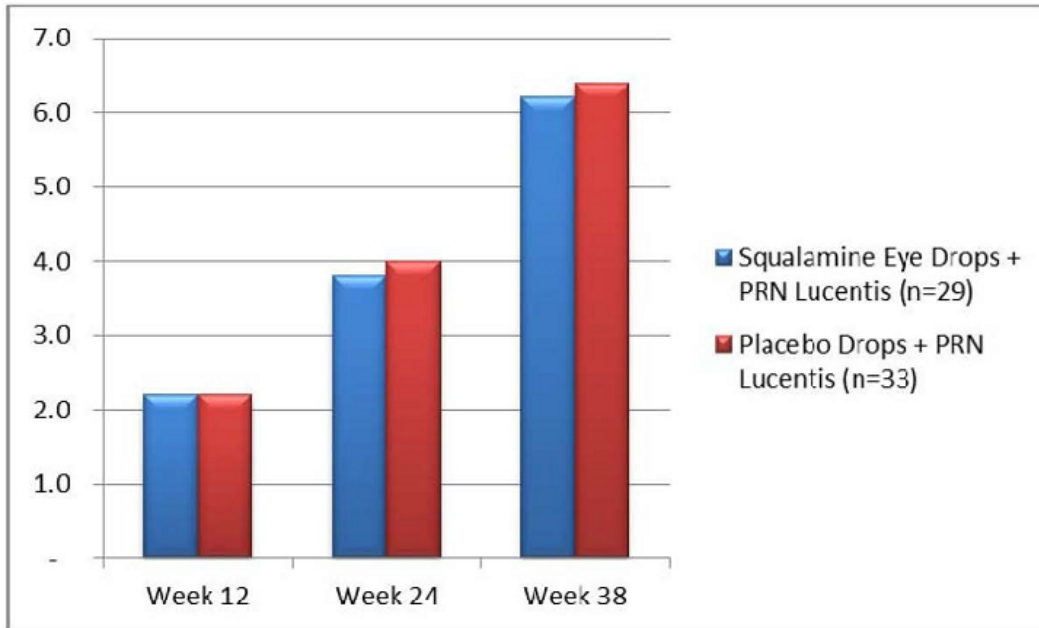
Percentage ≥ 4 Line VA Gainers



Percentage ≥ 5 Line VA Gainers



Mean Number of Injections



Includes baseline Lucentis Injection and any injections required per protocol up to the displayed timepoints



Interim Safety Results

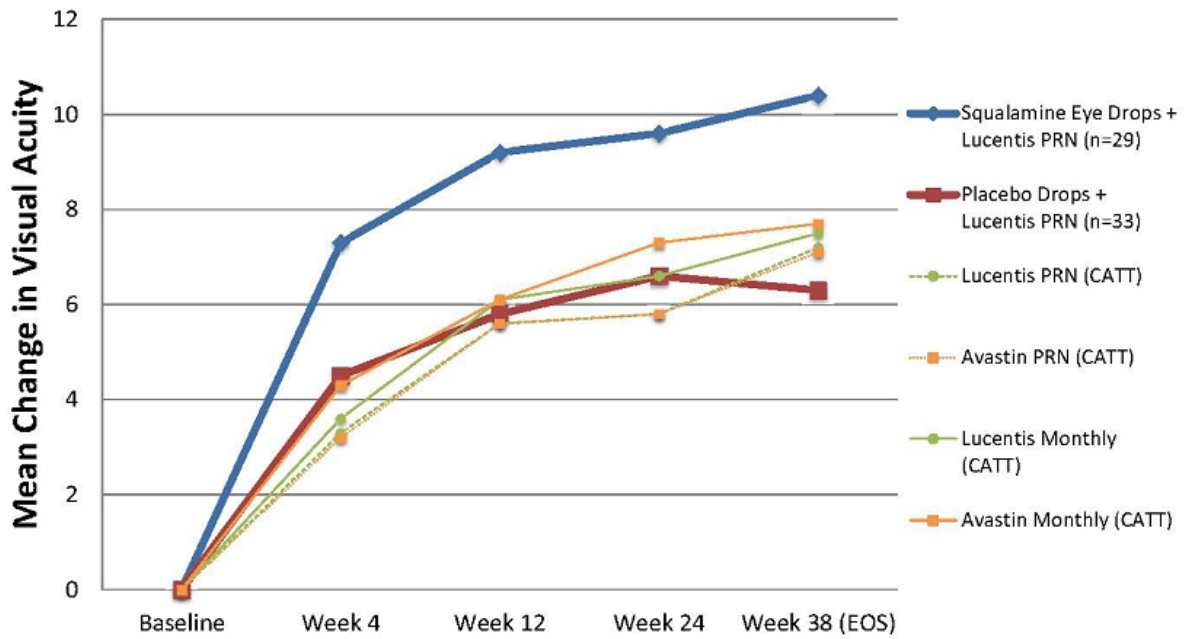
- Eye drops were well tolerated
- No difference in ocular or systemic AE profile versus placebo eye drops
- No differences in intraocular pressure
- No cataract formation in active group



Historical Clinical Studies



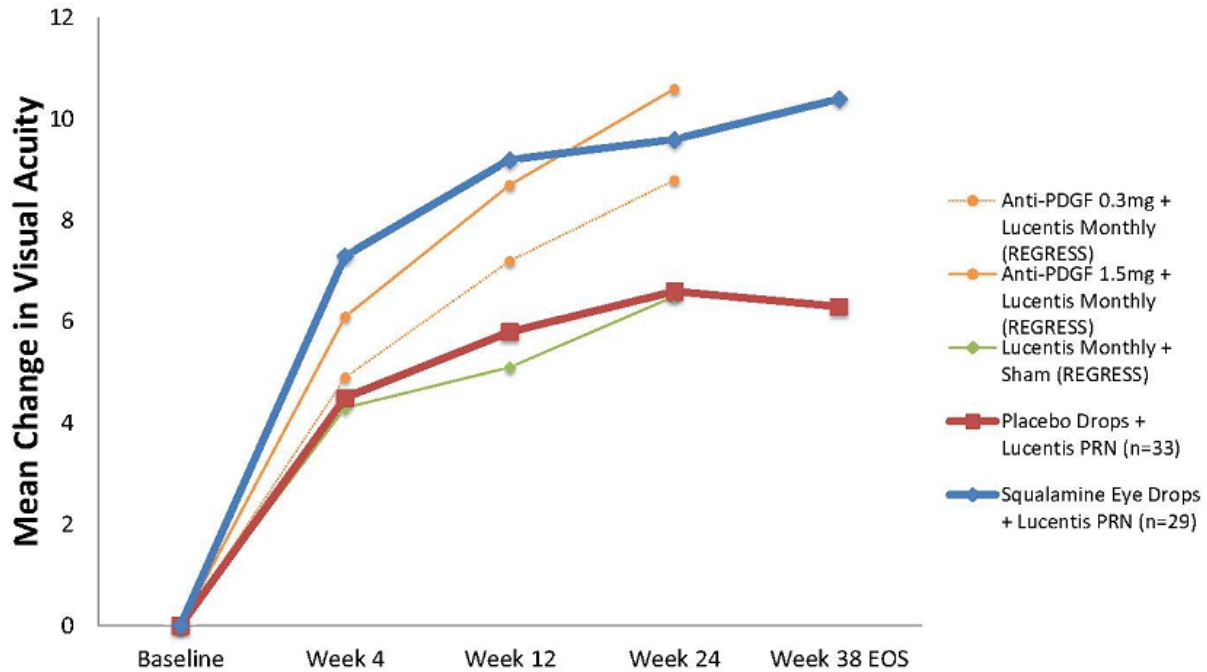
Mean Visual Acuity vs CATT*



*Comparison of AMD Treatments Trials (Avastin®-Lucentis® Study)
The CATT Research Group, N Engl J Med 2011; 364:1897-1908, May 19, 2011



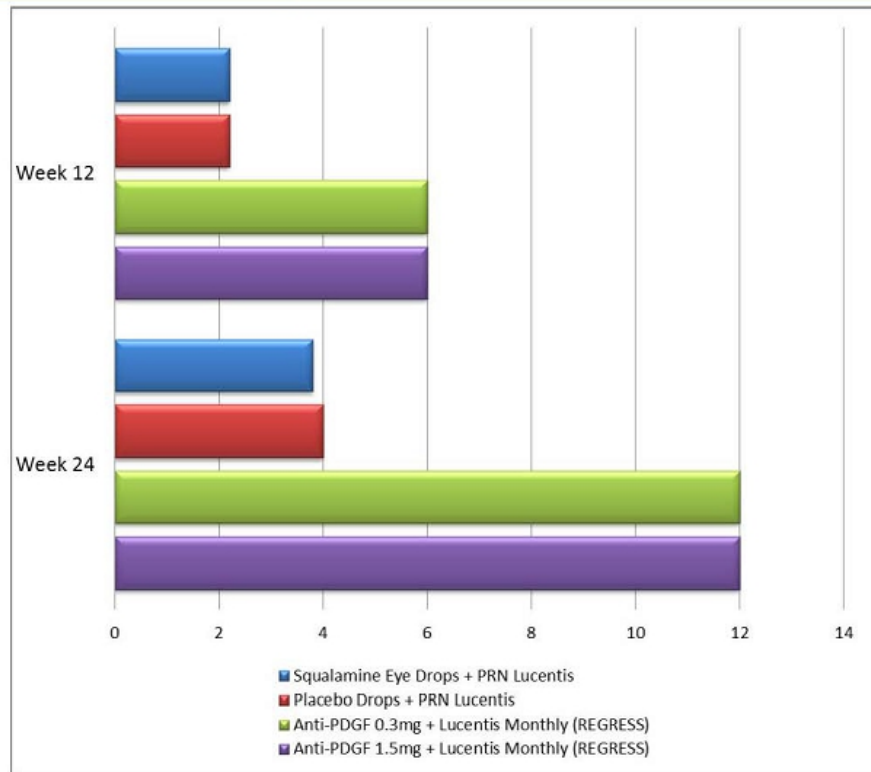
Mean Visual Acuity vs REGRESS*



*Kaiser PK et al. Angiogenesis 2013



Number of Injections to Achieve Visual Acuity Benefit vs REGRESS Study



Conclusions

- Squalamine eye drops combined with Lucentis PRN demonstrated marked improvements over the Lucentis PRN + placebo drops in:
 - Mean gains in Visual Acuity ($p=0.18$)
 - % of patients gaining ≥ 15 letters ($p=0.025$)
 - % of patients with ≥ 4 and ≥ 5 line vision gain ($p=0.022$ and $p=0.059$)
- Vision results in Lucentis PRN + placebo drops (comparator arm) consistent with CATT results with similar PRN dosing and retreatment regimen



Conclusions

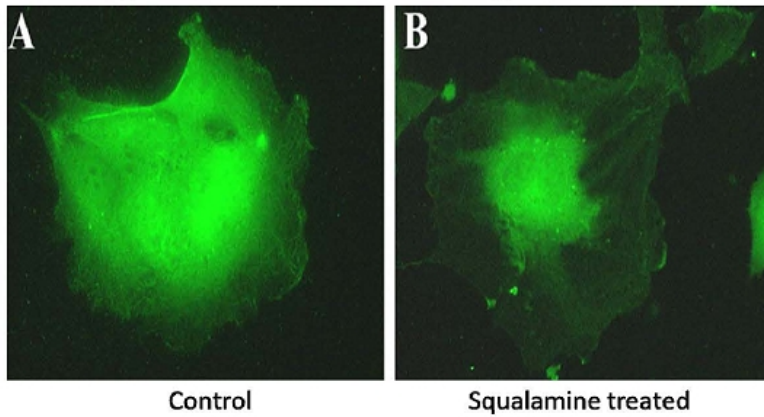
- Squalamine eye drop combination therapy comparable to reported visual improvements with anti-VEGF & anti-PDGF intravitreal combination development program
 - However, vision benefit was achieved with a mean of 3.8 injections over 24 weeks, compared with 12 total injections with anti-PDGF & anti-VEGF combination
- Enrolled population included large lesions, diabetics, and occult only lesions, representative of the entire wet AMD market



Squalamine Mechanisms

- Squalamine inhibits multiple growth factors and pathways in the angiogenic process including:
 - VEGF
 - PDGF
 - bFGF

Does so through calmodulin binding & chaperoning effect



Precedent for Topical Therapy in Posterior Segment Disease

- TG100801
- Nepafenac
- Mecamylamine

- Several lines of evidence in literature for small molecule diffusion to posterior ocular tissues
 - Transscleral route
 - Periocular route



Summary

- The interim results of the Squalamine eye drop program demonstrate dramatic vision gains across the full spectrum of exudative AMD compared to Lucentis + placebo drop regimen
- Excellent safety and tolerability profile to date
- Full interim data presentation at an ophthalmology conference in 3Q- 4Q 2014
- Completion of full study expected in Q1 2015



Ohr Pharmaceutical Announces Positive Interim Top-line Clinical Results from Phase II Study of Squalamine Eye Drops in Patients with Wet AMD

- *Patients treated with Squalamine eye drops plus Lucentis[®] PRN demonstrated a 65 percent additional relative benefit in visual acuity versus placebo eye drops plus Lucentis PRN*
- *Percentage of Squalamine plus Lucentis PRN-treated patients gaining three, four and five lines in visual acuity was more than double the placebo plus Lucentis PRN arm*
- *Conference call and webcast scheduled for 8:30 a.m. EDT*

NEW YORK, June 24, 2014 -- Ohr Pharmaceutical, Inc. (Nasdaq:OHRP), an ophthalmology research and development company, today announced positive top-line interim results for its double-masked, placebo-controlled Phase II clinical trial of Squalamine eye drops in patients with wet age-related macular degeneration (wet AMD). The data demonstrated a positive benefit in visual function across multiple clinically relevant endpoints, including a mean change in visual acuity at the end of study visit for the interim analysis group of +10.4 letters with Squalamine eye drops plus Lucentis[®] PRN versus +6.3 letters in the placebo eye drops plus Lucentis PRN arm, a 65 percent additional relative benefit ($p=0.18$). The visual acuity improvements were seen as early as four weeks and the relative difference in visual acuity between the two treatment arms continued to increase throughout the study.

All patients in the study received an initial Lucentis injection followed by Lucentis as needed (PRN) based on clinical response. The two treatment arms were Squalamine eye drops administered twice daily plus Lucentis PRN ("Squalamine" arm or group) versus standard-of-care treatment: placebo eye drops administered twice daily plus Lucentis PRN ("placebo" arm or group).

This planned interim analysis was conducted on the first 62 patients (29 treated in the Squalamine arm, 33 treated in the placebo arm), who completed the entire nine months of the treatment protocol (representing approximately 50 percent of the targeted study population). The Squalamine-treated group demonstrated improved best-corrected visual acuity (BCVA) gains relative to the placebo group at all timepoints evaluated from four to 38 weeks. In the interim analysis group, 48.3 percent of Squalamine-treated patients showed BCVA gains of ≥ 15 letters (≥ 3 lines) on a standard ETDRS eye-chart, compared with 21.2 percent in the placebo arm at the end of the study ($p=0.025$). In addition, patients receiving Squalamine drops were more than twice as likely to gain ≥ 4 and ≥ 5 lines of vision compared with patients in the placebo eye drop arm (≥ 4 lines $p=0.022$, ≥ 5 lines $p=0.059$). Importantly, the visual acuity gains for the placebo eye drop arm were consistent with those observed in previous clinical studies using Lucentis monotherapy treatment. Squalamine eye drops were well tolerated and had a comparable safety profile to placebo eye drops.

"The beneficial effects of Squalamine on visual acuity that we've seen thus far, through its inhibition of multiple angiogenic growth factors and pathways, and in particular, the improvement in gains of three or more lines in vision compared with the placebo group, are truly remarkable," said Dr. Jason Slakter, Chief Medical Officer of Ohr and retina specialist at Vitreous-Retina-Macula Consultants of NY. "Visual acuity is the most clinically relevant endpoint for back-of-the-eye disorders. For wet-AMD patients, such enhanced gains of visual acuity over standard-of-care anti-VEGF treatments, and the restoration of vision lost to this devastating disease of the elderly using a convenient eye drop therapy is a very important clinical outcome."

In the interim analysis, there were no significant differences in the frequency of Lucentis PRN injections, which was the primary endpoint of the study. The mean number of Lucentis injections was 6.2 for the Squalamine arm and 6.4 for the placebo arm, which included the baseline injection and any injections required up to and including the final study visit for the interim analysis group.

“The interim results seen in this trial are encouraging,” said Dr. Jeffrey S. Heier, Director of Vitreoretinal Service at Ophthalmic Consultants of Boston, member of Ohr’s scientific advisory board, and study investigator. “The potential to treat patients with a non-invasive therapeutic option to provide additional visual acuity benefit over the current standard-of-care, and do it with a less than monthly injection frequency, would be a significant advance in the treatment of retinal neovascular disease and beneficial for our patients. We look forward to the results of the full data set and Phase III trials.”

“We are very excited by these promising interim results from this wet-AMD trial,” said Dr. Irach B. Taraporewala, President and Chief Executive Officer of Ohr. “The data further validate not only the clinical utility of non-invasive topical eye drop therapies for macular and retinal disorders, but also the soundness of our company’s drug development science, and our proprietary formulation technologies that enable topical dosing to achieve positive therapeutic effects in back-of-the-eye disorders. These data give us a clear path for future registration studies, and we plan to discuss Phase III registration study design and the path forward with the regulatory authorities in the coming months.”

The company plans to present the full data from this interim analysis at an ophthalmology conference in the second half of this year, with final clinical trial data expected in the first calendar quarter of 2015.

Study Design

The ongoing clinical trial (Study OHR-002) is a randomized, double-masked, placebo-controlled Phase II study to evaluate the efficacy and safety of Squalamine eye drops used in combination with Lucentis PRN for the treatment of the advanced, exudative form of age-related macular degeneration (AMD), also known as “wet AMD.” The trial has enrolled 142 newly diagnosed, treatment naïve patients, of which the first 62 had completed the treatment period at the time of the interim analysis. The inclusion criteria allowed for patients with visual acuity levels similar to previous Lucentis trials, varying lesion sizes up to 12 disc areas in size, and any lesion composition, including classic and occult only types of wet AMD. The trial also included diabetics with no concomitant diabetic retinopathy.

Patients received an initial intravitreal injection of Lucentis at study entry, and then underwent a 1:1 randomization to receive a daily dose of either Squalamine eye drops or placebo eye drops administered twice daily for nine months. Patients had monthly follow-up clinic visits, where they were evaluated and retreated as needed with Lucentis if pre-specified clinical criteria were met. The primary endpoint was the mean number of Lucentis injections and secondary endpoints included visual acuity as well as diagnostic imaging outcomes. The planned interim analysis was performed when more than 50 percent of the study population finished their final study visit.

Conference Call and Webcast

Ohr Pharmaceutical is planning a live teleconference call and webcast to provide additional information on the interim clinical trial results. Details of the call are as follows:

Tuesday, June 24, 2014, 8:30 a.m. EDT

Toll Free: 877-407-0789

International: 201-689-8562

Webcast and Slide Deck: www.ohrpharmaceutical.com

Replays through July 8, 2014:

Toll Free: 877-870-5176

International: 858-384-5517

Replay PIN: 13585479

About Squalamine Eye Drops

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 (VEGF), platelet-derived growth factor (PDGF), and basic fibroblast growth factor (bFGF). Ohr Pharmaceutical has developed a novel eye drop formulation of Squalamine for the treatment of wet AMD, designed for convenient, patient self-administration, which may provide clinical utility for this patient population and other 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 (OHR-002) 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 (IST) are evaluating Squalamine eye drops for the treatment of proliferative diabetic retinopathy, retinal vein occlusion, and diabetic macular edema, with one additional IST expected to be initiated in diabetic macular edema in the third calendar quarter of 2014.

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 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. 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

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Lucentis[®] is a registered trademark of Genentech, Inc.

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