



||||| Science for a **better life**

[Home](#) / [Investors](#) / [News](#) / [Archive](#) / [Investor News 2008](#)

August 19, 2008

Bayer HealthCare and Regeneron Announce VEGF Trap-Eye Achieved Durable Improvement in Vision over 52 Weeks in a Phase 2 Study in Patients with Age-related Macular Degeneration

Study patients, on average, received only two additional doses following a 12-week fixed dosing period

Leverkusen, Germany and Tarrytown, NY, August 19, 2008 - Bayer HealthCare AG and Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced that patients with wet age-related macular degeneration (AMD) receiving VEGF Trap-Eye in a Phase 2 extension study on a PRN (as needed) dosing schedule continued to show highly significant improvements at 52 weeks in the primary and key secondary endpoints of retinal thickness (an anatomic measure of

<https://www.investor.bayer.com/en/nc/news/archive/investor-news-2008/investor-news-2008/bayer-healthcare-and-regeneron-announce-vegf-trap-eye-achi...>

Mylan Exhibit 1092

treatment effect) and vision gain. The 12-week primary endpoint results from the fixed-dosing period of the study were presented at the 2007 Retina Society conference in September 2007. The 32-week results of the Phase 2 study were presented at the 2008 Association for Research in Vision and Ophthalmology (ARVO) meeting in Fort Lauderdale, Florida. A full analysis of the 52-week results of the Phase 2 study will be presented at the 2008 meeting of the Retina Society on September 26-28, 2008 in Scottsdale, Arizona.

In this double-masked, prospective, randomized, multi-center Phase 2 trial, 157 patients were randomized to five dose groups and treated with VEGF Trap-Eye in one eye. Two groups initially received monthly doses of 0.5 or 2.0 milligrams (mg) of VEGF Trap-Eye (at weeks 0, 4, 8, and 12) and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg of VEGF Trap-Eye (at baseline and week 12). Following the initial 12-week fixed-dosing phase of the trial, patients continued to receive therapy at the same dose on a PRN dosing schedule based upon the physician assessment of the need for re-treatment in accordance with pre-specified criteria. Patients were monitored for safety, retinal thickness, and visual acuity. These data represent the final one-year analysis from the 52-week study.

Patients receiving four monthly doses of VEGF Trap-Eye, either 2.0 or 0.5 mg, for 12 weeks followed by PRN dosing thereafter, achieved mean improvements in visual acuity versus baseline of 9.0 letters ($p < 0.0001$) and 5.4 letters ($p = 0.085$), respectively, and mean decreases in retinal thickness versus baseline of 143 microns ($p < 0.0001$) and 125 microns ($p < 0.0001$) at week 52, respectively. During the subsequent PRN dosing phase, patients initially dosed on a 2.0 mg monthly schedule received, on average, only 1.6 additional injections and those initially dosed on a 0.5 mg monthly schedule received, on average, 2.5 injections.

For all dose cohorts combined, there was a 5.3 mean letter gain in visual acuity versus baseline at the week 52 evaluation visit ($p < 0.0001$). The mean decrease in retinal thickness for all dose groups combined at week 52 was 130 microns versus baseline ($p < 0.0001$). During the week 12 to week 52 PRN dosing period, patients from all dose groups combined received, on average, only two

<https://www.investor.bayer.com/en/nc/news/archive/investor-news-2008/investor-news-2008/bayer-healthcare-and-regeneron-announce-veg-f-trap-eye-achi...>

Mylan Exhibit 1092

additional injections.

VEGF Trap-Eye was generally well tolerated and there were no drug-related serious adverse events. There was one reported case of culture-negative endophthalmitis/uveitis in the study eye and one arterial thrombotic event, neither of which was deemed to be drug-related. The most common adverse events were those typically associated with intravitreal injections.

"The 52-week results underline that VEGF Trap-Eye has the potential to significantly reduce retinal thickness and improve vision," said Dr. Kemal Malik, member of the Bayer HealthCare Executive Committee responsible for product development. "The further development of this compound is important for millions of people worldwide who suffer from this devastating ocular disease."

"Based upon retinal physicians' feedback, there remains a significant unmet medical need for a treatment for wet AMD that can reliably improve visual acuity over time without the need for monthly intravitreal injections," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "We are excited about these study findings and the potential for VEGF Trap-Eye to fulfill this need pending the results of our ongoing Phase 3 clinical studies."

About the Phase 3 Program in Wet AMD

Regeneron and Bayer HealthCare initiated a Phase 3 global development program for VEGF Trap-Eye in wet AMD in August 2007. In two Phase 3 trials VIEW 1 and VIEW 2 (VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet age related macular degeneration), the companies are evaluating VEGF Trap-Eye dosed 0.5 mg every 4 weeks, 2 mg every 4 weeks, or 2 mg every 8 weeks (following three monthly doses) in direct comparison with ranibizumab (Lucentis®, a registered trademark of Genentech, Inc.) administered 0.5 mg every four weeks according to its U.S. label during the first year of the studies. PRN dosing will be evaluated during the second year of each study. The VIEW1 study (www.regeneron.com/vegfttrap_eye.html) is currently enrolling patients in the United States and Canada and the VIEW2 study (www.view2study.com) is currently enrolling patients in Europe, Asia Pacific, Japan, and Latin America. The companies are collaborating on the global development of VEGF Trap-Eye

<https://www.investor.bayer.com/en/nc/news/archive/investor-news-2008/investor-news-2008/bayer-healthcare-and-regeneron-announce-veg-f-trap-eye-achi...>

Mylan Exhibit 1092

for the treatment of wet AMD, diabetic eye diseases, and other eye diseases and disorders. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

About VEGF Trap-Eye

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body whose normal role is to trigger formation of new blood vessels (angiogenesis) to support the growth of the body's tissues and organs. It has also been associated with the abnormal growth and fragility of new blood vessels in the eye, which lead to the development of wet AMD. The VEGF Trap-Eye is a fully human, soluble VEGF receptor fusion protein that binds all forms of VEGF-A along with the related Placental Growth Factor (PlGF). VEGF Trap-Eye is a specific and highly potent blocker of these growth factors. Blockade of VEGF, which can prevent abnormal blood vessel formation and vascular leak, has proven beneficial in the treatment of wet AMD.

About Wet AMD

Age-related Macular Degeneration (AMD) is a leading cause of acquired blindness. Macular degeneration is diagnosed as either dry (nonexudative) or wet (exudative). In wet AMD, new blood vessels grow beneath the retina and leak blood and fluid. This leakage causes disruption and dysfunction of the retina creating blind spots in central vision, and it can account for blindness in wet AMD patients. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe.

About Bayer

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. Bayer HealthCare's aim is

<https://www.investor.bayer.com/en/nc/news/archive/investor-news-2008/investor-news-2008/bayer-healthcare-and-regeneron-announce-veg-f-trap-eye-achi...>

Mylan Exhibit 1092

to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

About Bayer Schering Pharma

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at www.bayerscheringpharma.de.

Forward-looking statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

January 16, 2019 17:29 CET

64.95

↓ -0.11 %

January 16, 2019 17:45 CET

10,931.24

↑ 0.36 %

<https://www.investor.bayer.com/en/nc/news/archive/investor-news-2008/investor-news-2008/bayer-healthcare-and-regeneron-announce-vegf-trap-eye-achi...>

Mylan Exhibit 1092

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.