



Fact Sheet

Bayer Schering Pharma Development Projects

Business Unit: Specialized Therapeutics

Development candidate VEGF Trap-Eye for wet AMD – Prospective enhanced option for treating the wet form of age-related macular degeneration (wet AMD)

- Potential for improving and stabilizing visual acuity (VA) in patients with wet AMD
 - Potential for a better dosing regimen compared to other available drugs for the same indication
 - Phase III study planned for 2007
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Status: June 2007

<p>Project description</p> <p>VEGF Trap-Eye is currently being tested in a Phase II trial for the treatment of the wet form of age-related macular degeneration. This eye disease is the most common cause of severely impaired vision and blindness among people over the age of 65 in the developed countries.</p> <p>Positive results from a planned interim analysis of the Phase II study were presented in May 2007 at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO).</p> <p>This analysis was made after the 12-week observation of the first 78 patients. Overall, a statistically significant</p>	<p>At a glance</p>
	<p>Name of the active substance</p> <p>VEGF Trap-Eye</p>
	<p>Type of substance</p> <p>Human soluble VEGF receptor fusion protein</p>
	<p>Administration form</p> <p>Injection into the vitreous body of the eye</p>

<p>improvement to the retina thickness (primary end point of the trial) and to sight (secondary end point) were observed. The retina thickness was reduced in all patient groups by 135 µm. In all of the groups, an average improvement to sight of 5.9 letters on the ETDRS chart was achieved. Apart from one patient, all those examined after 12 weeks showed stable or improved vision. Patients who only received a single dose displayed a reduction in retina thickness and an improvement to their sight over the entire period under observation of 12 weeks. The improvement to vision was significantly greater at the time of the interim analysis among those patients receiving monthly treatment.</p> <p>In the phase II study, VEGF Trap-Eye was generally well tolerated. The most common side effects were typically connected with the type of application – injection into the vitreous of the eye.</p> <p>Bayer HealthCare and Regeneron are planning the start of a phase III clinical trial program with VEGF Trap-Eye in the second half of 2007.</p> <p>Age-related macular degeneration (AMD) Age-related macular degeneration (AMD) is one of the most common non-infectious acquired causes of blindness. Macular degeneration is diagnosed either as dry (non-exudative) or wet (exudative). In the case of wet AMD, new blood vessels grow behind the retina, leaking blood and fluid. The collections of fluid cause swelling and disrupt the normal functioning of the retina, leading to "blind spots" in the central field of vision and can result in blindness among patients with wet AMD. Those patients affected lose their sight due to new blood vessels in the part of the eye responsible for the sharp vision. Around 90% of AMD-related cases of blindness are due to wet AMD. In the USA and in Europe, wet AMD is the main cause of severely impaired vision and blindness among people over 65 years of age.</p>	<p>Targeted Indication Age-related macular degeneration (AMD)</p> <hr/> <p>Mode of action Blockage of growth factors (VEGF-A and PIGF) and thus prevention of the formation of new blood vessels (antiangiogenesis)</p> <hr/> <p>Status</p> <ul style="list-style-type: none"> ▪ Currently undergoing Phase II trials ▪ Completion of study and publication of final results planned for 2007 ▪ Start of Phase III study planned in second half of 2007 <hr/> <p>Collaborating partner Regeneron Pharmaceuticals Inc. Tarrytown, NY, USA www.regeneron.com</p>
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VEGF Trap-Eye

VEGF (Vascular Endothelial Growth Factor) is a natural growth factor that stimulates the formation of new blood vessels (angiogenesis) and is produced by the body during the growth of tissue and organs, as well as in healing wounds. VEGF is also connected to the abnormal formation of new vessels and their fragility in the eye, which leads to the development of wet AMD. Few drugs that have already been registered have shown that the vision in patients suffering from wet AMD can be stabilized and improved by blocking VEGF.

VEGF Trap-Eye is a human, soluble VEGF receptor fusion protein, which binds all types of VEGF-A as well as the related placental growth factor (PlGF). VEGF Trap-Eye specifically blocks these growth factors and therefore has a high potential for efficacy. This prevents the formation of new blood vessels, which plays a major role in the development of wet AMD.

Bayer HealthCare and Regeneron are jointly developing VEGF Trap-Eye for the treatment of wet AMD, diabetic macular edema, and other eye diseases and indications. Bayer HealthCare and Regeneron will also market the product together and share the profits made outside the USA. Regeneron has the exclusive marketing rights within the USA.

Phase II study with VEGF Trap-Eye

In the 12-week, multicenter Phase II trial, a total of 159 patients are being examined. The participants are randomly divided into 5 groups and treated in one eye with VEGF Trap-Eye. Two of the five groups receive three doses (0.5 or 2.0 mg VEGF Trap-Eye) every four weeks. The other three groups each receive a single dose (0.5, 2.0, or 4.0 mg VEGF Trap-Eye). The patients are monitored over a period of 12 weeks with regard to safety and efficacy (retina thickness and vision).

<p>The retina thickness is determined using optical coherence tomography (OCT); the scans are evaluated at an independent center. The vision is defined according to the total number of letters correctly identified on the ETDRS (Early Treatment Diabetic Retinopathy Study) chart. A patient is classified as maintaining vision (stable vision) if the patient has lost fewer than 15 letters in the ETDRS letter score.</p>	
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Bayer HealthCare

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 and as Bayer HealthCare Pharmaceuticals in the US and Canada. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide.

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, Hematology/Cardiology, Oncology, Primary Care, Specialized Therapeutics 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.

Research and Development at Bayer Schering Pharma

Bayer Schering Pharma concentrates its R&D activities on innovative treatment approaches for diseases with a high unmet medical need to improve patients' quality of life and prolong lives. In this context, Bayer Schering Pharma focuses on its core competencies and its many years of experience. Thus, Bayer Schering Pharma holds a leading position in many therapeutic fields: for example, in the treatment of hemophilia and multiple sclerosis, in contrast media and oral contraception. We are also striving for a leading position in oncology. With new approaches in cancer therapy, for

cardiovascular diseases, gynaecological therapies and in molecular imaging, Bayer Schering Pharma aims to become an innovation leader in these fields. In addition, Bayer Schering Pharma further develops products already on the market in order to improve their application and/or extend their range of indications.

Contacts:

Dr. Jost Reinhard, Tel.: +49 30 468 15062

E-mail: jost.reinhard@bayerhealthcare.com

Frank Richtersmeier, Tel.: +49 30 468 17661

E-mail: frank.richtersmeier@bayerhealthcare.com

Forward-looking statements

This information contains forward-looking statements based on current assumptions and forecasts made by Bayer Group 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 our public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.