

QLT AND CIBA VISION SEEK TO EXPAND THE INDICATION FOR VISUDYNE

Supplemental new drug application submitted to FDA for eye conditions beyond age-related macular degeneration

For Immediate Release

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ATLANTA, GEORGIA and VANCOUVER, CANADA—CIBA Vision Corporation, the eye care unit of Novartis AG (NYSE:NVS), and QLT Inc. (NASDAQ:QLTI; TSE:QLT) today announced the filing of a supplemental new drug application (sNDA) for Visudyne™ (verteporfin for injection) therapy with the United States Food and Drug Administration (FDA) for the treatment of eye diseases beyond age-related macular degeneration (AMD), the leading cause of blindness among people over the age of 50.

Visudyne has already been approved for commercial use in AMD patients with predominantly classic choroidal neovascularization (CNV) in 22 countries, including the U.S., Canada, European Union, and Australia. CNV is a growth of abnormal blood vessels under the central part of the retina, or macula. These vessels leak fluid and cause scar tissue that destroys central vision, resulting in a deterioration of sight.

QLT and CIBA Vision seek to expand the initial indication to include patients with other ocular conditions characterized by CNV. These other diseases include pathologic myopia (PM), ocular histoplasmosis syndrome (OHS), angioid streaks, CNV due to certain retinal abnormalities, and idiopathic causes, among others.

The specific expanded label requested is for the treatment of patients with predominantly classic subfoveal choroidal neovascularization (CNV) caused by AMD, or with subfoveal CNV secondary to other macular diseases.

This supplemental filing is based primarily on new safety and efficacy findings that were presented at the Association for Research in Vision and Ophthalmology meeting in May 2000 and recently submitted for publication in a leading peer-reviewed ophthalmology journal.

The companies have requested a priority review from the FDA within a six-month period as there is no current satisfactory treatment for the majority of patients with these conditions. A similar request for expanded labeling will be made in the European Union by the end of 2000.

“As global acceptance of Visudyne continues to grow with new countries granting marketing clearance, it is exciting to expand the use of this therapy to provide hope for patients faced with the threat of losing their sight due to other ocular diseases,” said Luzi von Bidder, President of CIBA Vision’s worldwide Ophthalmics Business Unit.

“In our fight against blindness,” said Dr. Julia Levy, President and Chief Executive Officer of QLT, “the prospect of saving the vision of patients developing these other conditions, often in the prime of their careers and the midst of raising their families, is significant particularly when existing treatment options are limited or non-existent.”

CNV due to Pathologic Myopia (PM)

CNV due to pathologic myopia is caused by abnormal blood vessels that grow under the center of the retina as a result of an abnormal elongation of the back of the eye associated with severe near-sightedness or myopia. It generally occurs among people over 30 years of age and can result in a progressive loss of vision for which there is no approved treatment for the majority of patients. The worldwide incidence of CNV due to pathologic myopia is estimated to be 50,000 new cases per year, excluding Asia where the incidence may be even greater due to a higher prevalence of pathologic myopia.

The results for patients with CNV due to pathologic myopia are based on a single study involving 120 patients with the condition who were enrolled in a Phase IIIb 24-month multi center randomized placebo-controlled study called the VIP (Verteporfin In Photodynamic therapy) Trial. At 12 months, patients showed a significant benefit from Visudyne therapy with respect to visual acuity, contrast sensitivity, lesion size, amount of leakage and other outcomes.

Specifically, 86.4% of patients receiving Visudyne therapy lost less than 3 lines of vision, or 15 letters, on a standard eye chart, compared to 66.7% of patients administered a placebo ($p=0.01$). More patients treated with Visudyne therapy (64%) compared to placebo (42%) had stable (plus or minus 4 letters on a standard eye chart) or improved visual acuity (greater than a 4 letter gain) at 12 months. Furthermore, Visudyne-treated patients (32%) were twice as likely as those patients on placebo (15%) to show an improvement of at least 5 letters of vision at the 12 month time point. At all follow-up visits starting at three months after the initial treatment, the mean visual acuity loss in the Visudyne group was one-third or less than that in the placebo group.

Patients in the study assigned to Visudyne received an average of 3.4 treatments during the 12-month period and are continuing to be followed for an additional 12 months.

Ocular histoplasmosis syndrome (OHS)

OHS is a condition caused by a fungal infection of the retinal area endemic to certain areas in the central and eastern United States. It can lead to severe, irreversible vision loss and is a leading cause of blindness in adults who have lived in the geographic areas where the soil mold *Histoplasma capsulatum* is found. The condition is caused by inhaling the fungus from soil or other areas that have been contaminated by the droppings of birds or bats. Annually, there are an estimated 100,000 people who are at risk for vision loss within this endemic area.

In an open-label safety study involving 26 patients with OHS, mean visual acuity scores increased from baseline by 6.8 letters at nine months after the initial treatment. Visual acuity scores improved by 5 or more letters from baseline in 54% of patients at the same time point, with 33% of patients gaining 15 or more letters of visual acuity at nine months. Mean contrast sensitivity scores also increased from baseline by 2.7 letters at nine months and contrast sensitivity scores improved 3 or more letters from baseline in 42% of patients at the same time point.

Safety of Visudyne therapy

Visudyne has a favorable safety profile in all patients treated with CNV. The most frequently reported adverse events found in clinical studies and attributed to the treatment include injection site events and visual disturbances. Based on additional commercial and clinical trial use, no new safety issues have been identified that suggest a change in the benefit-risk ratio, thereby demonstrating that Visudyne is safe, independent of the patient population studied.

Rationale for filing

Visudyne therapy has been shown to be safe and efficacious in predominantly classic subfoveal CNV secondary to AMD and subfoveal CNV in PM. Additionally, the initial effect on visual function in ocular histoplasmosis appears consistent with findings in pathologic myopia. Based on these findings, the supplemental NDA seeks approval of Visudyne therapy for PM, OHS and a variety of other diseases characterized by CNV, in particular those in which the lesions are typically predominantly classic, even though the etiology of the formation of CNV is different for each disease, such as multifocal choroiditis, angioid streaks, certain retinal abnormalities, idiopathic or unknown causes, and many other rare conditions. Together these conditions, along with AMD, PM and OHS, comprise virtually 100% of all subfoveal CNV cases.

Background information

Visudyne therapy is a two-step procedure that can be performed in a doctor's office. First Visudyne is injected intravenously into the patient's arm, then a non-thermal laser light is shone into the patient's eye to activate the drug. Visudyne therapy uses a specially designed laser that produces the low level, non-thermal 689nm light required to activate the drug. These lasers have been developed by two of the world's leading laser companies, Coherent Inc. (NASDAQ: COHR), based in California, and the Carl Zeiss Group, based in Germany.

Visudyne therapy is being co-developed for various ocular conditions by CIBA Vision and QLT Inc. CIBA Vision markets the product worldwide while QLT is responsible for manufacturing. Visudyne therapy is protected by a series of U.S. and foreign-issued patents on composition of matter, formulations and manufacturing, and the method of use in treating AMD and other conditions.

Background on CIBA Vision and QLT

With worldwide headquarters in Atlanta, Georgia, USA, CIBA Vision is a global leader in research, development and manufacturing of optical and ophthalmic products and services, including contact lenses, lens care products, ophthalmic surgical products and ophthalmic pharmaceuticals. CIBA Vision products are available in more than 70 countries. For more information, you are invited to visit the CIBA Vision web site at www.cibavision.com.

CIBA Vision is the eye care unit of Novartis AG, a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 1999, the Group (including Agribusiness) achieved sales of CHF 32.5 billion and invested more than CHF 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis employs about 82,400 people and operates in over 140 countries around the world. CIBA Vision's Ophthalmics Business Unit will become part of Novartis Pharmaceuticals after December 31, 2000, and will be called Novartis Ophthalmics.

QLT Inc. is a world leader in the development and commercialization of proprietary pharmaceutical products for use in photodynamic therapy, a new field of medicine utilizing light-activated drugs in the treatment of disease. QLT's innovative science has advanced photodynamic therapy beyond applications in various cancers towards breakthrough treatments in ophthalmology and autoimmune disease. For more information, you are invited to visit QLT's web site at www.qltinc.com.

Visudyne™ is a trademark of Novartis AG

The foregoing information contains forward-looking statements which involve known and unknown risks, uncertainties and other factors which may cause the actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. Such factors include, but are not limited to: risks associated with the commercialization of Visudyne™ including patient and physician demand for the treatment; dependence on corporate relationships; manufacturing uncertainties; uncertainty of pricing and reimbursement; uncertainties relating to clinical trials and product development; QLT's history of operating losses and uncertainty of future profitability; competition; QLT's rapid growth; uncertainty regarding patents and proprietary rights; product liability claims and insurance; no assurance of regulatory approval; government regulation; uncertainty of QLT's access to capital; QLT's anti-takeover provisions; and volatility of QLT's common share price; among others, all as described in QLT's Annual Report on Form 10-K and Novartis AG's Form 20-F on file with the U.S. Securities and Exchange Commission.

Editors Please Note:

Outside of North America, the European Union, Switzerland, Australia, Argentina, Brazil, and Malta, the use of Visudyne therapy is currently investigational. Only patients who are currently enrolled in clinical trials sponsored by QLT and CIBA Vision are eligible for treatment at this time. Patients and practitioners seeking additional information may view our web site at www.visudyne.com or call the patient/practitioner hotline in North America, 1-800-821-2450.

- 30 -

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For more information, you are invited to visit the CIBA Vision web site at www.cibavision.com or the Visudyne web site at www.visudyne.com

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