

## **EU COMMISSION APPROVES VISUDYNE™ FOR THE TREATMENT OF WET AMD IN THE EUROPEAN UNION**

**For Immediate Release**

**July 28, 2000**

ATLANTA, GEORGIA and VANCOUVER, CANADA—CIBA Vision, the eye care unit of Novartis (NYSE: NVS), and QLT Inc. (NASDAQ: QLTI; TSE: QLT) announced today that the European Commission has granted Marketing Authorisation for Visudyne™ (verteporfin) for the treatment of wet age-related macular degeneration (AMD), the leading cause of blindness among people over the age of 50.

Specifically, the Commission's decision is in line with the Committee of Proprietary Medicinal Products' (CPMP's) opinion to recommend Visudyne for the treatment of AMD in patients with predominantly classic subfoveal choroidal neovascularization (CNV) throughout the European Union. Medical experts estimate that of the 500,000 new patients that develop wet AMD every year around the world, 40-60% will develop predominantly classic lesions during the progression of their disease. Patients with this condition lose their ability to read, drive and recognize faces in as little as two months to three years. Currently, only 10 - 15% of the estimated 500,000 patients who develop wet AMD worldwide every year are eligible for existing treatments.

“Visudyne therapy is the first approved drug treatment for this devastating condition. Now with approval throughout the European Union, Visudyne will provide new hope to many of the approximately 200,000 patients in the European Union who lose their vision from wet AMD every year,” said Luzi von Bidder, President of CIBA Vision's worldwide Ophthalmics Business Unit. “This much needed therapy will be available to eye care professionals and their patients across the European Union within the next few weeks.”

With this approval, Visudyne is now approved in most of the markets in the Western Hemisphere. In addition to the EU countries, Visudyne is currently approved and commercially available in Argentina, Brazil, Canada, Malta, Switzerland and the United States. Regulatory applications are pending in Australia, New Zealand, South Africa, Mexico and India, among many others. While regulatory reviews are ongoing, Visudyne is currently being made available under various expanded access programs in more than 15 countries.

“We are excited about this new approval for Visudyne,” said Dr. Julia Levy, President and Chief Executive Officer of QLT. “This is another major milestone in making Visudyne therapy available to improve the lives of so many people on a worldwide basis.”

The approval was based on two 24-month randomized, double-masked, placebo-controlled Phase III trials known as the TAP (Treatment of AMD with Photodynamic therapy) Investigation. The results of the TAP Investigation after 12 months were published in the October 1999 issue of *Archives of Ophthalmology*, a leading international medical journal. The primary finding of these trials showed that in 243 patients with predominantly classic CNV, vision remained stable or improved in 67% of patients treated with Visudyne therapy compared to 39% of patients on placebo (p<0.001).

The 24-month results from the TAP Investigation were presented in May at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO) and demonstrated that the beneficial effect and the favorable safety profile of Visudyne therapy observed at the 12-month time point have been maintained out to two years. These results also showed that fewer treatments are required in the second year.

“With this effective new therapy now available in the European Union, it is increasingly important to heighten the awareness of this condition among the elderly,” said Professor Gisele Soubrane from Creteil Hospital near Paris, France. “Despite the high prevalence of AMD, according to a recent study, only 30% of adults are familiar with the condition. We encourage everyone over the age of 50 to see their eye care professional in order to identify their risk of developing AMD and to define their specific follow-up schedule.”

### **About AMD and Visudyne therapy**

Wet AMD is characterized by the formation of abnormal blood vessels (choroidal neovascularization or CNV) that grow under the central part of the retina, called the macula. These vessels leak fluid and eventually cause scar tissue, which destroys central vision. 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. The drug is then activated by shining non-thermal laser light into the patient’s eye.

Visudyne therapy involves the use of a specifically designed laser that produces the low level, non-thermal 689 nm 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 Carl Zeiss, based in Germany.

Visudyne is being co-developed for ocular conditions by CIBA Vision Corporation, the eye care unit of Novartis AG, and QLT Inc., formerly known as QLT PhotoTherapeutics Inc. CIBA Vision markets the product worldwide while QLT retains responsibility for manufacturing the product.

Visudyne therapy is protected by a series of U.S. and foreign-issued patents that cover the 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](http://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.

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](http://www.qltinc.com).

*Visudyne™ is a trademark of Novartis AG*

*Editors Please Note:*

Outside of North America, Europe, Argentina and Brazil, the treatment of wet AMD with Visudyne therapy is currently investigational. Only patients who are currently enrolled in clinical trials sponsored by QLT and CIBA Vision or under expanded access programs meeting local requirements in certain other countries, are eligible for treatment at this time. Patients and practitioners seeking additional information may view our web site at [www.visudyne.com](http://www.visudyne.com).

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QLT Inc. is listed on The Nasdaq Stock Market under the trading symbol “QLTI” and on The Toronto Stock Exchange under the trading symbol “QLT”.

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: risks associated with the commercialization of Visudyne™ therapy including patient and doctor demand for the treatment; dependence on corporate relationships; manufacturing uncertainties; uncertainty of pricing and reimbursement; uncertainties relating to clinical trials and product development; QLT Inc.'s history of operating losses and uncertainty of future profitability; competition; QLT Inc.'s rapid growth; uncertainty regarding patents and proprietary rights; QLT Inc.'s product liability claims and insurance; no assurance of regulatory approval; government regulation; QLT Inc.'s uncertainty of access to capital; anti-takeover provisions; and volatility of common share price; among others, all as described in the Company's Annual Information Form on Form 10-K.