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## *news release*

### **QLT AND NOVARTIS PROVIDE UPDATE ON PHASE II VISUDYNE STUDIES**

*Statistically Significant Six-Month Placebo Controlled Trial Results in the First Prospective Trial Targeting Patients with Minimally Classic Subfoveal Wet AMD*

#### **For Immediate Release**

**December 17, 2002**

VANCOUVER, CANADA and BULACH, SWITZERLAND—QLT Inc. (NASDAQ: QLTI; TSX: QLT) and Novartis Ophthalmics, the eye health unit of Novartis AG (NYSE: NVS), today announced statistically significant preliminary results of the six-month vision outcomes of patients being treated with Visudyne® for minimally classic wet age-related macular degeneration (AMD). This announcement follows a presentation given to the independent Data and Safety Monitoring Committee (DSMC) along with the results of two other Phase II Visudyne studies.

The Visudyne in Minimally Classic (VIM) study was comprised of 117 patients equally randomized to one of three treatment arms: placebo; Visudyne standard regimen; or Visudyne reduced fluence (reduced light intensity). Early outcomes at six months showed that the mean change in visual acuity scores of patients in both Visudyne treatment arms (loss of 1.6 letters in the reduced fluence group and loss of 2.8 letters in the standard fluence group) were statistically significantly better than the loss of 9.4 mean letter change in patients receiving placebo (p value of 0.008 and 0.024 respectively). This study will continue until at least the twelve-month period to confirm longer-term benefit. More details of the six-month results will be presented at the Macula Society meeting in Florida in late February 2003.

The DSMC also reviewed data from two other studies of 60 patients each which are seeking improved treatment outcomes with altered regimens for Visudyne treatment. They are referred to as ADD-V (the addition of an anti-inflammatory called Voltaren Ophthalmic®), and VALIO studies (an altered light treatment using delayed light after Visudyne in occult AMD).

Neither of the two studies showed additional vision benefit over the standard Visudyne regimen at three-months which may not be unexpected at this early time point. Angiographic and visual acuity outcomes for VALIO at the six-month time point will be submitted for presentation at the Association for Research Vision in Ophthalmology (ARVO) meeting in Florida in May 2003.

All three studies confirmed the safety of Visudyne with no additional concerns observed in any of the treatment regimens used.

“The six-month results of the VIM study were very encouraging,” said Paul Hastings, president and chief executive officer of QLT. “Although these data need to be followed up to determine longer-term benefit, this is the first time we have observed prospectively positive visual acuity outcomes of Visudyne in patients with minimally classic subfoveal AMD.”

“We are fully committed to exploring all options to fight blindness with Visudyne therapy,” said Luzi von Bidder, head of Novartis Ophthalmics. “It is great to have such promising VIM data for the many patients for whom there is no approved drug treatment currently available, and who are currently at a high risk of becoming legally blind.”

QLT and Novartis are working to enhance Visudyne therapy through a comprehensive, on-going clinical trial program involving more than 1,000 patients.

Visudyne therapy is a two-step procedure. Following intravenous administration, Visudyne is activated by a non-thermal laser light. This process is known as photodynamic therapy. Visudyne selectively targets abnormal blood vessels under the retina, resulting in a reduction in their growth, without affecting normal/healthy retina tissue. This in turn stops the leakage associated with wet AMD.

### **About AMD**

AMD is the leading cause of legal blindness in people over the age of 50. Its associated vision loss has been shown to significantly decrease quality of life. Everyday tasks such as driving and walking can be severely affected. Awareness of the condition and treatment in the early stages of the disease are essential in order to help patients take the necessary steps to visit their physician and begin therapy to halt progression of AMD. Through its unique mode of action, Visudyne provides the chance to reduce the risk of moderate and severe vision loss and thereby preserve vision long-term.

AMD occurs in two forms: dry and wet. The dry form is associated with atrophy cell death of the central retina. The wet form is caused by growth of abnormal blood vessels (CNV) under the central part of the retina or macula. These vessels leak fluid and blood that lead to the development of scar tissue that destroys the central retina. This results in a deterioration of sight over a period of months to years. “Occult” and “classic” are terms used to describe the different patterns of CNV leakage as seen on fluorescein angiography. Classic CNV appears as a well-demarcated area of hyperfluorescence in the early-phase frames of the angiogram. The boundaries of occult CNV are often poorly defined or difficult to demarcate and often appears as hyperfluorescence in the late-phase frames of the angiogram.

### **About Visudyne**

Visudyne therapy, the only drug approved for the treatment of some forms of wet AMD, has treated over 200,000 patients worldwide. Visudyne is commercially available in more than 65 countries for the treatment of predominantly classic subfoveal CNV and in over 25 countries for occult subfoveal CNV caused by AMD. It is also approved in over 45 countries, including the EU, U.S. and Canada, for the treatment of subfoveal CNV due to pathologic myopia (severe near-sightedness). In some countries Visudyne is also approved for presumed ocular histoplasmosis or other macular diseases.

Visudyne is generally well tolerated and has an excellent safety profile. Potential side effects include injection site reactions, headaches, back pain, blurring, decreased sharpness and gaps in vision, and in 1-5% of patients a substantial decrease in vision with partial recovery in some patients. People should avoid direct sunlight for five days to avoid sunburn. People with porphyria should not be treated. For more information, visit [www.visudyne.com](http://www.visudyne.com).

*Visudyne® is a trademark of Novartis AG.*

The foregoing press release contains forward-looking statements that can be identified by terminology such as “promising data,” “will be,” “are planned,” “are committed to” or by discussions regarding the evaluation of early trial data or potential new indications or treatment methods for existing products. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results and assumptions 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 development and commercialization of the treatment, including uncertainties relating to manufacturing, clinical trials, registration, pricing and reimbursement; patient and physician demand for the treatment; competition; any uncertainty regarding patents and proprietary rights; outcome of litigation claims, product liability claims and insurance; government regulation; anti-takeover provisions; dependence on corporate relationships; volatility of share prices; QLT Inc.’s rapid growth, its history of operating losses and uncertainty of future profitability, its access to capital; and additional information and other factors as described in detail in QLT Inc.’s Annual Information Form on Form 10-K and recent and forthcoming quarterly reports on Form 10-Q, and Novartis AG’s Form 20-F, and other filings with the US Securities and Exchange Commission and Canadian Securities Regulatory authorities.

### **Background on Novartis Ophthalmics and QLT Inc.**

**QLT Inc.** (NASDAQ: QLTI; TSE: QLT) is a global biopharmaceutical company dedicated to the discovery, development, and commercialization of innovative therapies to treat cancer, eye diseases and immune disorders. Combining expertise in ophthalmology, oncology and photodynamic therapy, QLT has commercialized two products to date, including Visudyne therapy, which is the most successfully launched ophthalmology product ever. For more information, visit our web site at [www.qltinc.com](http://www.qltinc.com).

**Novartis Ophthalmics:** With worldwide headquarters in Bulach, Switzerland, Novartis Ophthalmics is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of age-related macular degeneration, eye inflammation, glaucoma, ocular allergies and other diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. The North American headquarters is based in Atlanta, Georgia. Novartis Ophthalmics products are made in Switzerland, France and Canada. For more information, visit [www.novartisophthalmics.com](http://www.novartisophthalmics.com) or [www.novartisophthalmics.com/us](http://www.novartisophthalmics.com/us).

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2001, the Group's businesses achieved sales of CHF 32.0 billion (USD 19.1 billion) and a net income of CHF 7.0 billion (USD 4.2 billion). The Group invested approximately CHF 4.2 billion (USD 2.5 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 74,000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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