

Matt Meehan  
Novartis Pharma Communications  
+41 61 324 4879 (direct)  
+41 79 592 1813 (mobile)  
matt.meehan@novartis.com

Corinne Hoff  
Novartis Global Media Relations  
+41 61 324 9577 (direct)  
+41 61 324 2200 (main)  
corinne.hoff@novartis.com

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

## **Novartis seeks European approval of Lucentis® for the treatment of patients with wet age-related macular degeneration (AMD)**

- *Lucentis the first investigational therapy to improve vision in patients with wet AMD*
- *EU filing follows US submission by Genentech*
- *Two Phase III studies show Lucentis maintains or improves vision in up to 96% of treated patients*

**Basel, March 2, 2006** – Novartis announced today the submission of Lucentis® (ranibizumab) for European Union approval for the treatment of neovascular age-related macular degeneration (“wet AMD”), which is the leading cause of blindness in people over age 60 in the western world<sup>1</sup>.

The European submission, done under the centralized procedure, is the latest in a series aimed at obtaining approvals for Lucentis worldwide. Novartis also submitted Lucentis for regulatory approval in Switzerland in February.

“Lucentis is the first agent to improve vision in patients with wet AMD, setting a new efficacy standard for the treatment of patients with this debilitating disease. We look forward to working closely with regulatory authorities to ensure the availability of Lucentis to patients as quickly as possible,” said Nicholas Franco, Global Head of Novartis Ophthalmics. “Novartis is committed to maintaining and improving the vision of people suffering from AMD. With Lucentis, we would be able to provide patients with another effective treatment for wet AMD.”

The EU submission follows positive one-year clinical data on the efficacy and safety of Lucentis from two pivotal Phase III trials (MARINA and ANCHOR) that demonstrated the ability of Lucentis to maintain or improve vision in nearly all patients treated. In both of the pivotal Phase III trials, Lucentis was shown to maintain or improve vision in up to 96% of patients treated, regardless of baseline lesion type, lesion size or baseline visual acuity of the patient.

In addition, the recently unmasked two-year efficacy and safety data from the MARINA study are consistent with results observed at one year, showing continued Lucentis treatment sustained the beneficial vision effects achieved during the first year of treatment, while the vision of patients in the sham-control group\* continued to decline over time. Results will be presented during ARVO, a medical congress held in Fort Lauderdale, Florida, from April 29 to May 4, 2006.

Lucentis works by inhibiting the growth of abnormal new blood vessels as well as leakage under the macula which lead to wet AMD disease progression and subsequent vision loss.

---

\* *In the sham-control group, the physician does not actually perform an injection.*

AMD is estimated to affect over 25 million people worldwide<sup>2</sup>. It is caused by growth of abnormal blood vessels also known as choroidal neovascularization (CNV) or ocular angiogenesis under the macula, the part of the retina that is responsible for central vision, required for activities such as reading, recognizing faces and driving. These vessels leak fluid and blood, causing the development of scar tissue that destroys the macula, leading to the loss of central vision over a period of months to years.

While existing agents have been shown to slow the progression of vision loss, there remains a large unmet need for novel therapy options for patients whose independence and quality of life continue to be significantly impacted by this debilitating disease.

#### **About Lucentis**

Lucentis (ranibizumab) is a humanized monoclonal antibody fragment designed to bind and inhibit VEGF-A, a protein that is believed to play a critical role in angiogenesis (the formation of and leakage from new blood vessels). Consequently Lucentis blocks abnormal new blood vessel growth and leakiness which leads to wet AMD disease progression and vision loss.

Lucentis is being developed by Genentech and the Novartis Ophthalmics Business Unit. Genentech retains commercial rights for Lucentis in the United States and Canada. Novartis has exclusive commercialization rights for the rest of the world.

#### **About AMD**

AMD is a major cause of painless central visual loss and is the leading cause of blindness for people over the age of 60 in the western world<sup>1</sup>. It affects over 25 million people worldwide<sup>2</sup>. AMD occurs in two forms: dry and wet<sup>1</sup>. The dry form is associated with atrophy of the central retina, or macula, that is required for fine vision used for activities such as reading, driving or recognizing faces. The wet form is caused by growth of abnormal blood vessels also known as choroidal neovascularization (CNV) or ocular angiogenesis under the macula. These vessels leak fluid and blood and cause scar tissue that destroys the macula. These changes result in a deterioration of vision over a period of months to years.

The foregoing press release contains certain forward-looking statements that can be identified by terminology such as “aimed at”, “will be”, “look forward”, “would be able to” or similar expressions, or by express or implied discussions regarding potential marketing approvals of Lucentis, or regarding any potential revenues from Lucentis. Such forward-looking statements involve known and unknown risks, uncertainties or other factors that may cause the actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that Lucentis will be approved for sale in any market or that it will reach any particular sales levels. In particular, management’s expectations relating to Lucentis could be affected by, among other things, uncertainties relating to clinical trials; unexpected regulatory actions or delays or government regulation generally; the ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; as well as factors discussed in the Company’s Form 20-F filed with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

#### **About Novartis Ophthalmics**

With worldwide headquarters in Basel, Switzerland, the Novartis Ophthalmics Business Unit 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. Novartis Ophthalmics

products are made in Switzerland, France, the United States and Canada. For more information, visit [www.novartisophthalmics.com](http://www.novartisophthalmics.com) or [www.us.novartisophthalmics.com](http://www.us.novartisophthalmics.com).

### **About Novartis**

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality low-cost generics and leading self-medication OTC brands. In 2005, the Group's businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 91,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

### **References**

<sup>1</sup>National Eye Institute. Age-Related Macular Degeneration: What You Should Know. US Department of Health and Human Services. National Institutes of Health. NIH Publication no.: 03-2294. Available at: <http://www.nei.nih.gov/health/maculardegen/webAMD.pdf>

<sup>2</sup>AMD Alliance International. Facts About AMD. Available at: [http://www.amdalliance.com/AMD\\_Information/facts\\_about\\_amd.html](http://www.amdalliance.com/AMD_Information/facts_about_amd.html).

###

### **Media Contacts**

#### **Corinne Hoff**

Novartis Global Media Relations  
+41 61 324 9577 (direct)  
+41 61 324 2200 (main)  
[corinne.hoff@novartis.com](mailto:corinne.hoff@novartis.com)

#### **Matt Meehan**

Novartis Pharma Communications  
+41 61 324 4879 (direct)  
+41 79 592 1813 (mobile)  
[matt.meehan@novartis.com](mailto:matt.meehan@novartis.com)