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eric.althoff@pharma.novartis.com**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG****FDA issues “approvable letter” for Certican®**

Basel, 30 August 2004 – Novartis Pharma AG has received an “approvable” letter from the U.S. Food and Drug Administration (FDA) for *Certican* (everolimus) in combination with *Neoral* (ciclosporin for microemulsion) for the prevention of rejection episodes following heart or kidney transplantation.

The FDA has requested that Novartis provide “additional” information supporting a safe and effective dosing regimen for the combination of everolimus and ciclosporin. The FDA had previously issued an approvable letter for *Certican* in October 2003 with a request for additional clinical data on dosing regimens. Novartis submitted data in response to the first approvable letter in February 2004. However, the FDA still believes that additional clinical studies on dosing are necessary.

Already approved for use in Europe, *Certican* is a novel proliferation signal inhibitor with immunosuppressive and antiproliferative properties. It is the latest innovation in the 20-year history of Novartis leadership in transplantation medication. The new drug application to the FDA for *Certican* included data from one of the most extensive drug development programs conducted to date for a transplantation product.

“Everolimus has been shown in clinical trials to provide important benefits that would be of significant value to transplant patients and their health care providers,” said Howard Eisen, M.D., Professor of Medicine at Temple University School of Medicine in Philadelphia.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Novartis Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland. Novartis Group companies employ about 80,000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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