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Basel, 20 September 2007

## European licence for Roche HIV drug Viracept recommended for re-instatement

### Measures put in place to restart the manufacturing and supply of HIV medicine

Roche announced today that the European Medicines Agency's (EMA) Committee for Human Medicinal Products (CHMP) has recommended that Viracept's marketing authorization is reinstated in Europe following its suspension earlier this summer. The Committee stated that it is satisfied with the actions taken by Roche. The positive recommendation is an important step towards lifting the suspension of the marketing authorization and will now go to the EU Commission for a final decision. Roche fully intends to re-supply Viracept (nelfinavir) once the suspension is lifted. However, it may take a few months for Viracept to be available again to prescribers and patients.

Viracept's license was suspended in August this year following the discovery that some of the drug batches contained a substance called ethyl mesylate (EMS).

"From the beginning of the recall, Roche acted responsibly, quickly and always in the best interests of patients. In a situation such as this, the most prudent action was to recall the medication" said William M. Burns, CEO of Roche's Pharmaceutical Division "We have worked tirelessly with the health authorities, physicians, health care providers, NGO treatment providers and, of course, patient groups on the recall with the full intention of re-supplying this medication."

The Viracept recall affects those countries where Roche-made Viracept is sold or distributed. This excludes the US, Canada and Japan where Pfizer has the responsibility to make and distribute Viracept.

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### **About Viracept**

Viracept (nelfinavir), a protease inhibitor is supplied by Roche outside the US, Canada and Japan. Viracept was first introduced by Roche in 1999.

### **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolism and central nervous system. In 2006 sales by the Pharmaceuticals Division totaled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche employs roughly 75,000 worldwide and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Roche's Diagnostics Division offers a uniquely broad product portfolio and supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories world-wide. For further information, please visit our website at [www.roche.com](http://www.roche.com).

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