

Basel, 27 August 1998

Fortovase® receives approval in the European Union

Fortovase®, a second generation HIV protease inhibitor, has received approval this week by the European Commission. Fortovase (saquinavir) is indicated in combination with antiretroviral agents for the treatment of HIV-1-infected adult patients.

Fortovase will become available to people with HIV infection throughout the European Union over the coming months. Fortovase has already been launched in the USA and Switzerland. Recently, Fortovase has also been approved in Australia, India and Mexico.

Fortovase is a new, more powerful formulation of Roche's saquinavir mesylate, the first protease inhibitor for the treatment of HIV disease, available under the brand name Invirase®. Over 200,000 people living with HIV have already been treated with Invirase. Clinical trials and experience to date have confirmed the clinical benefit, safety and tolerability of the compound.

Roche is also active in the development and marketing of diagnostic tests, such as Polymerase Chain Reaction (PCR) technology, which quantifies levels of HIV in blood. In 1994, Roche's Amplicor HIV-1-Monitor® became the first commercial test to accurately and precisely measure quantities of HIV-1 RNA in the blood ("viral load"), with a limit of quantification at 400 copies/ml. In June of 1998, Roche has filed a marketing application with the US regulatory authority FDA for an ultrasensitive test (limit of quantification at 50 copies/ml). A similar application in Europe is forthcoming.

Roche, headquartered in Basel, Switzerland, is a world leader in research-based healthcare with its principal business in pharmaceuticals, diagnostics, vitamins, and fragrances and flavours. Roche discovers and develops new compounds for marketing as prescription drugs in key therapeutic areas such as diseases of the nervous system, virology, infectious diseases, oncology, cardiovascular diseases, inflammatory and autoimmune diseases, dermatology, metabolic disorders and respiratory diseases.