

Basel, 17 November 1997

Fortovase® launched in the USA

Fortovase® (saquinavir), the new soft gelatin formulation of saquinavir was launched today in the United States of America. Fortovase®, developed by F. Hoffmann-La Roche Ltd, Basel, had been cleared for marketing by the US Food and Drug Administration (FDA) recently.

Fortovase® is indicated for the treatment of HIV infection in combination. Fortovase® is an effective and safe treatment for HIV disease. Fortovase® is currently also under review by regulatory authorities in the European Union and other countries.

Saquinavir mesylate was the first protease inhibitor available for the treatment of HIV disease with the brand name Invirase®. Ongoing drug development activities led to the new formulation which is introduced under the name Fortovase®. Given at the approved dose of 1200 mg three times a day with meals, Fortovase® provides an increased drug exposure of 8 to 10 times compared with the current, hard gel formulation of saquinavir.

The approval of Fortovase® was based in part on study NV15355 which showed that a significantly greater proportion of patients, who received Fortovase® plus two nucleoside analogues, achieved viral load reductions to below the limit of detection (400 copies/mL), as compared to those patients who have received Invirase® plus to nucleoside analogues at 16 weeks. Fortovase® is a more potent drug than Invirase® because the bioavailability and, more important, the drug exposure (the amount of drug absorbed in the bloodstream), results in a significant increase in antiviral activity.

Data were presented on the first-ever head-to-head trial comparing the antiviral efficacy of two HIV protease inhibitors, Fortovase® and Crixivan® (indinavir sulfate) in combination with other antiretroviral drugs at the 6th European Conference on Clinical Aspects and Treatment of HIV-Infection, Hamburg, Germany, 11-15 October '97. Preliminary results from the so-called "Cheese Study", demonstrates that Fortovase® +AZT+3TC and indinavir+AZT+3TC regimens were equally effective in suppressing viral load at week 12 of treatment. However, a greater increase in CD4 cell count was witnessed on the Fortovase® arm versus indinavir arm.

Roche is a world leader in original research and development in the health care field and has a long history of bringing important innovative products for the fight against AIDS to the market, including Hivid®, Invirase®, Cymevene® and Roferon®- A. Outside of North America and Japan, Roche also markets Viracept®, a protease inhibitor developed by Agouron.

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. Roche's Amplicor HIV-1-Monitor Test was the first commercial test to accurately and precisely measure quantities of HIV-1 RNA in the blood ("viral load"). The Amplicor HIV-1-Monitor has been available in most European countries since 1994, and since June 1996 in the USA.