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Roche Aids Drug Invirase cleared for the EU market

On October 4, 1996, the European Commission granted an EU-wide marketing authorisation for Roche's AIDS drug **Invirase (Saquinavir) for use in combination with antiretroviral nucleoside analogues** for the treatment of HIV-infected adult patients with advanced or progressive immunodeficiency. In June 1996, Invirase was recommended for approval by the CPMP (Committee for Proprietary Medicinal Products).

This approval of Invirase represents a significant improvement in the treatment of people with HIV disease in the EU member states. Resulting from the latest AIDS research, **initiation of combination therapy at an early stage** of this disease is now recommended. With the availability of Invirase the therapy of HIV disease becomes now **more effective and better tolerable** for patients.

Invirase was the first representative of the new class of treatments for HIV disease, the proteinase inhibitors, to enter clinical development. With a clinical programme covering more than 5.000 participants, Invirase is the proteinase inhibitor which has undergone the most extensive clinical research. Data from new studies demonstrate that patients treated with combinations including Invirase have **reductions of virus in the blood up to a median of 99.9% (2.97 log)** and **significant increases in CD4 cell counts** (a measure of the immune system). A special programme initiated by Roche provided Invirase to approximately 12.000 persons with HIV disease outside of the clinical development programme. All these studies show that Invirase is **effective, very well tolerated** and has a low level of interactions with other drugs used in the treatment of persons with HIV disease. The **development of resistance to Invirase is slow** and has no negative impact on the clinical benefit of other currently available proteinase inhibitors.

New Drug Applications for the marketing of Invirase have been filed globally and approvals have already been granted in USA, Canada, Australia, Switzerland and several countries in South America and Asia.

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