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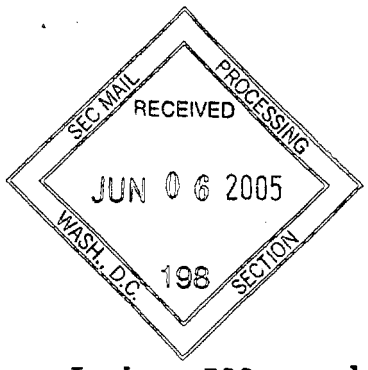
Group News



SUPPL

Basel, 27. May, 2005

European approval for Roche's new Invirase 500 mg tablet for the treatment of HIV

New Invirase 500 mg tablet significantly reduces pill burden for patients

Roche announced today the European marketing approval for its new 500 mg formulation of Invirase (saquinavir mesylate), an effective and well tolerated protease inhibitor used in the treatment of HIV infection. The new 500 mg tablet will simplify the dosing regimen for patients by reducing the daily tablet count by more than half, from five tablets twice-daily to two tablets twice-daily.

Antiretroviral therapies have become more and more effective and have transformed HIV infection into more of a chronic disease with patients living much longer than before [1]. As such it is particularly important to offer effective therapies to patients that are both well tolerated and convenient. The new Invirase 500 mg formulation will meet the needs of patients by offering a simpler and more convenient treatment option with excellent efficacy and a well established tolerability profile. Patients can easily switch from the current 200 mg capsule to the new 500 mg tablets, continuing to benefit from Invirase's high antiviral efficacy but with far more convenience.

"The launch of the 500 mg tablet is a further example of Roche's continuing commitment not only to the treatment of HIV but also to the development of medicines that more closely meet the needs of patients" said William M. Burns, CEO of Roche's Pharmaceutical Division.

"The reduced pill burden offered by the new Invirase 500 mg tablet will make boosted Invirase a much more attractive treatment option for patients and will encourage its use in early as well as advanced stages of HIV disease, " said Dr Anton Pozniak, Consultant Physician and Senior Lecturer at Chelsea and Westminster Hospital, London UK.

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Invirase is approved for use in combination with a low dose of another protease inhibitor (PI), ritonavir in combination with other antiretroviral drugs. Boosted Invirase has been shown in numerous clinical trials [2,3] to be highly potent with an excellent tolerability profile and limited toxicity. Invirase is recommended as a first line boosted PI in the International AIDS Society (IAS) guidelines which gave it the highest possible clinical evidence based rating [4].
Invirase 500 mg received FDA approval in the USA after priority review on December 18, 2004.

About Boosted Invirase

Invirase, originally approved by the FDA in 1995, was the first HIV protease inhibitor on the market. Its introduction represented a major milestone in the treatment of HIV/AIDS. In December 2003, the FDA approved Invirase for use in boosted dosing regimens with ritonavir (1000 mg Invirase/100 mg ritonavir bid). Co-administering Invirase with ritonavir enhances therapeutic blood levels of the drug and enables simplified dosing.
Data from the Staccato clinical study show reductions in patients' HIV RNA recorded in the first 24 weeks on therapy that are the best ever seen in a large cohort of patients given HAART. Some 96% of patients achieved viral load reductions to <400 HIV RNA copies/ml and 89% were shown to have undetectable levels (<50 HIV RNA copies/ml). Over the 24 week induction phase of the study, these reductions in patient viral load were accompanied by a median increase of CD4 cells of 109 cells/mm3.

Introduction of Invirase 500 mg

The new Invirase 500 mg tablet has a film coating for ease of swallowing and is comparable in size to the small Invirase 200 mg capsule. The 200 mg formulation of Invirase will remain available for those patients who want to continue to use it. Timelines for the launch of the new Invirase 500 mg tablet will differ from country to country depending on local regulations.

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 a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004 sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech

and Chugai. For further information: www.roche.com

More information

-Roche in HIV: www.roche.com/pages/downloads/company/pdf/mbhiv05e.pdf

-Roche and HIV: www.roche-hiv.com

-Health Kiosk: HIV, AIDS: www.health-kiosk.ch/start_aids.htm

References:
1. UNAIDS. AIDS Epidemic: Update 2004 and World AIDS Day 2004 (UNAIDS/WHO, December 2004)
2. Dragsted UB, Gerstoft J, Pedersen C et al. JID. 2003;188:635-642.
3. Youle M, Gerstoft J, Fox Z et al. 2nd IAS. Paris, France, 2003; Poster LB23
4. Yeni PG, Hammer SM, Hirsch MS et al. JAMA 2004; 292/2:251-265.