



Investor update

July 10, 2002

PROCESSED

AUG 01 2002

THOMSON
FINANCIAL

SUPPL

RECD S.E.C.
JUL 22 2002
1086

Head-to-head HIV study showed significant benefit for boosted Saquinavir over boosted Indinavir

Data from the MaxCmin1 trial, the first large, randomized study to compare "boosted" HIV protease inhibitor regimens, showed that boosted saquinavir (saquinavir 1000 mg with ritonavir 100 mg) reduced HIV to undetectable levels (<400 copies/mL) in more patients than boosted Crixivan® (Indinavir 800 mg with ritonavir 100 mg) at 48 weeks. Results of the study were presented in an oral session today at the XIV International AIDS Conference (IAC), being held in Barcelona, Spain, July 7-12.

The analysis of 48-week data showed that boosted saquinavir reduced HIV viral load to undetectable levels (less than 400 copies/mL) in 68 percent of patients, while boosted Indinavir reduced HIV viral load to undetectable levels in 53 percent of patients (p = 0.014), according to the most stringent intent-to-treat analysis.

Significantly more patients withdrew from the study due to side effects in the Indinavir arm (41 percent) versus the saquinavir arm (28 percent; P= 0.025). Among patients who completed 48 weeks of therapy, HIV RNA was suppressed to below the limit of quantification in 93 percent of patients in the boosted saquinavir arm and in 90 percent of patients in the boosted Indinavir arm.

Additionally, at week four, fasting total cholesterol, LDL cholesterol and triglyceride levels increased more from baseline in the boosted Indinavir arm versus the boosted saquinavir arm: 17 percent versus 9 percent, 21 percent versus six percent and 29 percent versus 13 percent, respectively (p<0.05 for all three comparisons).

"The results of the MaxCmin1 study show that, at the dosage of 1000/100 mg twice-daily, boosted saquinavir has excellent efficacy in the treatment of HIV-infected patients. More important, it is now quite clear that only low doses of ritonavir - 100 mg twice-daily - are needed to boost saquinavir," said Dr. Julio S.G. Montaner, Chair of AIDS Research, St. Paul's Hospital, University of British Columbia in Vancouver. "Furthermore, in the MaxCmin1 study, treatment discontinuation was actually more common in the boosted Indinavir arm. Good tolerability can be an important determinant of HIV treatment success."

More About MaxCmin1

A total of 92 patients had at least one grade 3 (severe) and/or grade 4 (life threatening) adverse event: 62 (39 percent) in the boosted Indinavir arm versus 30 (20 percent) in the saquinavir arm (p=0.0004). The number and type of grade 3 or 4 adverse events in the Indinavir and saquinavir arms, respectively, included: cardio-pulmonary (5 and 1), renal (13 and 1), gastrointestinal (19 and 17), nervous system (8 and 4), dermatological (18 and 4), laboratory (21 and 21), and other (20 and 12).

dlw 7/23

MaxCmin1 is an ongoing study that was designed and coordinated by the Copenhagen HIV Investigator Program (CHIP). Patients from 14 countries in North and South America and Europe participated in the MaxCmin1 study. The primary objective of the study, which enrolled 317 patients, was to evaluate differences in virological failure between saquinavir (n=148) and Indinavir (n=158), each co-administered with a small 100 mg dose of ritonavir, at 48 weeks. (Eleven patients who were randomized did not initiate therapy.) At baseline, no difference between the study arms were observed in demographic, clinical or laboratory variables, nor in the use of any antiretroviral drug prior to inclusions or at baseline.

"Boosting" Protease Inhibitors

Co-administering protease inhibitors with a low dose of ritonavir is an investigational treatment strategy known as "boosting." By using low, "non-therapeutic" doses of ritonavir, the metabolism of other protease inhibitors, such as saquinavir, can be inhibited, resulting in higher and more consistent levels of the "therapeutic" protease inhibitor.

More About Saquinavir Soft Gel Capsules (FORTOVASE®)

The most frequently reported adverse events at least possibly related to treatment with saquinavir soft gel capsules and of at least moderate intensity - observed in trials evaluating the approved 1200 mg three-times-daily dosing regimen - include nausea (17.8 percent), diarrhea (15.6 percent), abdominal discomfort (13.3 percent) and dyspepsia (8.9 percent). Saquinavir soft gel capsules should not be co-administered with astemizole, terfenadine, ergot derivatives, cisapride, midazolam or triazolam, due to the potential for serious and/or life-threatening events.

Concomitant use with lovastatin or simvastatin is also not recommended; caution should be exercised with other HMG-CoA reductase inhibitors metabolized by the CYP3A4 pathway. Exacerbation of chronic liver dysfunction has been reported in patients treated with saquinavir soft gel capsules. Patients should be informed that redistribution or accumulation of body fat may occur in patients receiving protease inhibitors and that the cause and long-term health effects of these conditions are not known at this time. There have also been reports of hyperglycemia, new onset or exacerbation of diabetes and of spontaneous bleeding in patients with hemophilia. Please refer to the complete product information for detailed safety information for saquinavir soft gel capsules.

More About Saquinavir Hard Gel Capsules (INVIRASE®)

Saquinavir hard gel capsules deliver the same active ingredient as saquinavir soft gel capsules, and the safety and drug interaction information provided above for saquinavir soft gel capsules also applies to saquinavir hard gel capsules. The saquinavir hard gel capsules product labeling warns that saquinavir hard gel capsules and saquinavir soft gel capsules are not bioequivalent and cannot be used interchangeably. When using saquinavir as part of an antiviral regimen saquinavir soft gel capsules is the recommended formulation. In rare circumstances, saquinavir hard gel capsules may be considered if it is to be combined with antiretrovirals, such as ritonavir, that significantly inhibit saquinavir's metabolism.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address needs for the prevention, diagnosis and treatment of disease, thus enhancing people's well being and quality of life.

Crixivan[®] is a registered trademark of Merck and Co.

Your IR contacts:

Dr. Karl Mahler Dr. Mathias Dick Dianne Young
Tel: +41 (61) 687 85 03 Tel: +41 (61) 688 80 27 Tel: +41 (61) 688 93 58
email: karl.mahler@roche.com email: mathias.dick@roche.com email:
dianne.young@roche.com

US investors please contact:

Richard Simpson
Tel: +41 (61) 688 48 66
email: richard.simpson@roche.com

With best regards,
Your Roche Investor Relations Team
F. Hoffmann-La Roche Ltd
Investor Relations
Grenzacherstrasse 68 / Postfach
4070 Basel
<http://ir.roche.com/>
email: investor.relations@roche.com
phone: ++41 61 688 88 80
fax: ++41 61 691 00 14