HIV-1 patients with an undetectable viral load can switch to VIRAMUNE® regardless of their CD4 count

Boehringer Ingelheim

Ingelheim/Germany, 16 September 2010 - Boehringer Ingelheim announced today that the European Commission has approved an update to the Summary of Product Characteristics (SmPC) for VIRAMUNE® (nevirapine) in the treatment of patients with HIV.

The label change means that HIV -1 patients with an undetectable viral load can switch to treatment with Viramune® regardless of their CD4 count.

A large body of clinical evidence demonstrates that the risk of hypersensitivity and/or hepatotoxicity in treatment-experienced HIV patients switching to Viramune® is **not** increased among those with an undetectable viral load ([1-4].

“This is good news for all HIV patients looking to change their HIV treatments to a Viramune®-based regimen because of drug resistance, side effects or drug interactions,” said Professor Jürgen Rockstroh, University Bonn. “Prescribing physicians will now no longer have to apply the CD4 count threshold when switching patients to a lipid-friendly regimen containing Viramune®.”

The decision followed a positive recommendation by the Committee for Medical Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA) who reviewed the clinical evidence and approved the new wording in the Viramune® Summary of Product Characteristics.

This new label change is based on data from more than 12,000 patients, including a meta-analysis of randomised prospective studies, a retrospective analysis of a single centre HIV cohort and observational studies (EuroSIDA cohort, ATHENA cohort and multi-cohort studies). [1-4] These studies found that the risk of hypersensitivity and/or hepatotoxicity in patients with an undetectable viral load switching to Viramune® is not increased in patients with higher CD4 counts (i.e. above the gender specific CD4-thresholds: women more than 250 cells/mm³, men more than 400 cells/mm³).

Notes to Editors

About Viramune®
Viramune® is a product of original research done at Boehringer Ingelheim. Viramune® was the first member of the non-nucleoside reverse transcriptase inhibitor (NNRTI) class of anti-HIV drugs and is indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents. This indication is based on one principal clinical trial that demonstrated prolonged suppression of HIV-RNA and

several smaller supportive studies. Studies have also shown that patients switching to Viramune® from a PI-based regimen demonstrate an improved lipid profile while maintaining viral suppression. The most clinically important adverse events associated with Viramune® are rash and hepatic events, which have included fatal cases. The greatest risk of severe rash and hepatic events occurs in the first six weeks of therapy. It is essential that patients be monitored for these reactions at all times, and intensively during the first few months of therapy. Viramune® should be discontinued and not restarted following severe hepatic, skin or hypersensitivity reactions.

Boehringer Ingelheim
The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 142 affiliates in 50 countries and more than 41,500 employees. Since it was founded in 1885, the family-owned company has been committed for 125 years to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.

In 2009, Boehringer Ingelheim posted net sales of 12.7 billion euro while spending 21% of net sales in its largest business segment Prescription Medicines on research and development.

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http://www.chem.info/news/2010/09/hiv-1-patients-undetectable-viral-load-can-switch-viramune%C2%AE-regardless-their-cd4-count?qt-most_popular=0

Links:
[1] http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2010/16_september_2010_hiv.html