



**Press release 2008-03-19**

## **Lipsovir<sup>®</sup> prevents cold sores. Phase III clinical trial results first to show prevention by early treatment.**

For the first time, a clinical phase III program has demonstrated that it is possible to prevent cold sores by early treatment initiation. The entire phase III program comprised almost 3000 patients in five studies, the pivotal trial being the largest ever conducted with 1443 patients treated out of 2437 recruited. Treatment with Lipsovir<sup>®</sup> prevented the development of cold sores in 42% of patients. In those patients who nevertheless developed a cold sore, the healing time and severity were significantly reduced.

Lipsovir<sup>®</sup> is a patented combination of hydrocortisone (an anti-inflammatory agent) and aciclovir (an antiviral agent) in a proprietary cream base developed by Medivir. Lipsovir<sup>®</sup> prevented cold sores significantly better than placebo ( $p < 0.0001$ ). Even though Medivir's proprietary cream base seemed to have increased the effect of aciclovir, Lipsovir<sup>®</sup>'s preventive effect was superior ( $p = 0.014$ ). The healing time of ulcerative recurrences was reduced by 1.5 days in comparison to placebo, which is a clinically highly meaningful reduction. Lipsovir<sup>®</sup> was well tolerated in all phase III studies.

"The phase III clinical program shows that Lipsovir<sup>®</sup> has clear advantages compared with the current standard treatment for cold sores. The results are remarkably good and it is very positive for patients with recurrent cold sores that over 40% of episodes could be prevented by Lipsovir<sup>®</sup>. No product on the market has been able to show a preventive effect. We therefore consider it important that patients with recurrent cold sores are given access to Lipsovir<sup>®</sup>", says Assoc. Professor Börje Darpö, Medivir's Vice President for Clinical Development.

The result of the comparison between Lipsovir<sup>®</sup> and placebo widely exceeded FDA's requirement. Before the start of the trial, a preventive effect of acyclovir had not been demonstrated. FDA therefore asked for a somewhat higher level of significance ( $p = 0.001$ ) for the comparison between Lipsovir<sup>®</sup> and aciclovir than was achieved. In addition to the strong preventive effect of Lipsovir<sup>®</sup>, analysis of all the available data from the entire development program will provide basis for a constructive dialogue with regulatory authorities. After this dialogue, the time for regulatory submissions can be more accurately specified.

"We have proven that the Lipsovir<sup>®</sup> concept works. The combination of an antiviral and an anti-inflammatory agent in our cream base prevents cold sores. We will now continue our contacts with potential marketing partners", says CEO Lars Adlersson.

### **Press Conference Invitation**

Medivir will hold a press conference today at 11 am at the IVA Conference Centre, Grev Turegatan 16, Stockholm (a light lunch will be served).

The phase III clinical trial results will be presented in detail with opportunities for discussion and questions. Medivir will be represented by its CEO Lars Adlersson, VP Clinical Development Assoc Prof Börje Darpö, the Lipsovir<sup>®</sup> Project Director Eva Arlander and Medivir's CFO/VP IR Rein Piir.

**For more information on Medivir, please see the company website: [www.medivir.se](http://www.medivir.se)**