



**Press Release 1 October 2008**

## **New Drug Application (NDA) for Lipsovir® submitted to US FDA**

Medivir has today submitted an NDA to the US Food & Drug Administration (FDA) for Lipsovir®, a topical product for prevention and treatment of cold sores. Lipsovir® is a patented combination of hydrocortisone (an anti-inflammatory agent) and aciclovir (an antiviral agent) in a proprietary cream base developed by Medivir.

"We had a pre-NDA meeting with the FDA in May 2008, at which the final results from the program were presented and discussed, as well as the format and time-lines of the submission. We have since then worked hard to finalize all documentation and we are very happy to announce that the NDA now has been submitted in accordance with our previously communicated time schedule. This was made possible by a very dedicated team and through collaboration with external experts and key opinion leaders", says Börje Darpö, MD, Vice President and Head of the development group at Medivir.

The clinical phase III program demonstrated that the development of cold sores can be prevented with early treatment initiation, an effect that available products for this indication lack. Lipsovir® thereby provides subjects with recurrent cold sores with a clinically important benefit compared to currently available products.

The results from the phase III program have been presented during the spring/summer of 2008 and showed that:

- 42% of subjects treated with Lipsovir® did not develop cold sores with blisters, ulcers and crusting, compared to 26% in the placebo group
- Lipsovir® reduced the healing time of cold sores by 1.5 days as compared to placebo
- Lipsovir® was well tolerated in all studied populations, including adolescents.

"It is a huge step forward for Medivir to file our first registration application. The partnership process continues, with the intention to liaise with one or several companies to help us commercializing the product globally", says Lars Adlersson CEO & President Medivir AB.

### **For additional information, please contact**

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