PRESS RELEASE 07th December 2000

Medivir's herpes cream ME-609 shows interesting results in phase II studies

Each year between 250 and 400 million outbreaks of oral herpes occur in the US, Western Europe and Japan. These are accompanied by unsightly lesions ("cold sores") around the mouth. Current medications do not adequately treat this condition. There is a considerable market need for a new and more effective treatment for oral herpes.

Medivir, in collaboration with AstraZeneca, has recently completed the phase II clinical study of ME-609 cream, a potential new treatment for oral herpes. Preliminary results from this study, conducted in North America, confirm that ME-609 cream is safe and well-tolerated and may be at least as effective, if not better, than existing products on the market.

The results indicated that ME-609 cream reduced the healing time of cold sores by 15% compared to placebo (ITT, p=0.084 based on log transformed data). However, interestingly only 50 patients who were treated with ME-609 cream developed classical cold sores after the commencement of treatment, in comparison to 70 in the group treated with placebo. This reduction in incidence of classical cold sores was surprising and statistically significant (ITT, p=0.016).

Aileen Allsop, VP and Head of Infection Therapy Area, AstraZeneca, commenting on these results said, "We have been very pleased with the way that Medivir has conducted the phase I and II clinical trials including the formulation of ME-609 cream in a professional and efficient way. However, we will not be continuing our collaboration with Medivir. This was a decision based on issues involving strategic portfolio management of our newly merged company."

Medivir has decided to find a new partner to continue the development of ME-609 cream. A future development partnership would continue to benefit from the expertise of Medivir's subsidiary CCS AB, which developed and produced the ME-609 cream for the phase II study.

Facts about the study
In collaboration with AstraZeneca, Medivir has developed the ME-609 cream for treatment of recurrent oral herpes (cold sores). The development work included this phase II study: a double-blind, placebo controlled, randomised efficacy and safety study carried out by leading university clinics in North America.

Patients with a history of sun-induced herpes simplex virus infections around the mouth were irradiated with UV light. Treatment then began after 48 hours, half of the patients were treated with ME-609 cream and half with an inactive placebo cream. The patients were monitored for efficacy and safety end-points including cold sore development, healing time, side effects etc.

Of the 380 treated patients (190 treated with ME-609 cream, 190 with placebo cream), 145 patients developed lesions (Intent-to-treat, ITT) whereof 120 patients developed classical cold sores after the commencement of treatment (2 days) but before day 7 (Intent-to-treat, ITT). The ITT population constituted the patient group which underwent final analysis to determine efficacy. It was a high quality clinical trial and the number of patients was sufficient to determine safety and efficacy of ME-609 cream .

Three main end-points are of primary clinical interest when evaluating treatment of cold sores: The incidence, time to healing (measured as time to loss of hard crust or to recover normal skin) and maximum lesion size. Because ME-609 cream is a new treatment principle it was not known at the start of this phase II proof-of-concept study which end-points would be influenced most by the ME-609 cream treatment.

Data and evaluation of the preliminary results
Preliminary results indicated that ME-609 cream is an effective treatment for herpes simplex virus induced cold sores. The ME-609 cream treatment showed a favourable safety profile in the study.

Of the ME-609 cream treated patients who developed classical cold sores, the healing time to loss of hard crust (primary efficacy end-point) was about 1 day shorter after treatment with ME-609 cream compared to placebo (i.e. 5.7 vs 6.7 days, ITT, p=0.084 based on log transformed data), corresponding to a 15% decrease of disease period.

Interestingly, 50 patients who were treated with ME-609 developed classical cold sores after the commencement of treatment, in comparison to 70 in the group treated with placebo (secondary end-point). This reduction in incidence of classical cold sores was surprising and statistically significant (ITT, p=0.016).

In addition, of the ME-609 cream treated patients who developed classical cold sores, the healing time to recover normal skin was reduced by approximately 1.7 days (i.e. 9.3 vs 11.0 days, ITT, p=0.037 based on log transformed data). Also, the maximum size of the classical cold sores in these patients was smaller after treatment with ME-609 cream (72 vs. 99 mm^2 ITT, p=0.010 based on log transformed data), a reduction of 27%.

In conclusion, we have obtained with these preliminary data statistically significant results in three out of four of the main clinically relevant end-points.

Telephone conference
Medivir invites you to a telephone conference at 3 PM today. Jonas Frick CEO, Johan Harmenberg Head of Clinical Development and Rein Piir CFO/IR will present and comment the results from the phase II study.
Please call + 46 8 600 53 81 cod 927056 for participation.

For further information please contact:

Jonas Frick, CEO: Tel +46 8-608 31 17, +46 70-648 67 61 or

Rein Piir, CFO/IR: Tel +46 8-608 31 23, +46 70-853 72 92