

## PRESS RELEASE



### **Preliminary results from the first Phase III-study of the ETEC-vaccine**

There are two phase III studies for the candidate ETEC vaccine against travellers diarrhoea both coordinated by Johns Hopkins School of Hygiene and Public Health in Baltimore, USA. These are in Guatemala and in Mexico.

The first study, with Professor David Sack as principal investigator, comprising 671 travellers has recently been completed.

Data analyses show that the primary clinical endpoint as defined was not met i.e. protection against travellers' diarrhoea caused by vaccine preventable ETEC infection. However, further preliminary analyses indicate a trend for protection against moderate to severe diarrhoea as opposed to mild cases. As a consequence an application for registration in Europe can not be submitted this year as planned.

More analyses are ongoing including laboratory parameters. The data from the first study will give us valuable information for the further development of the clinical program.

The second study started in November 1999 in collaboration with SmithKline Beecham Biologicals, licensee for the worldwide rights outside the Nordic countries. Recruitment should be completed this summer. So far the study has included more than 200 travellers and the work is progressing well. This study is conducted with vaccine produced in accordance with the commercial product specification.

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