

Diese Meldung kann unter <http://www.presseportal.de/pm/53037/1536161/eans-news-intercell-announces-initiation-in-the-u-s-of-a-phase-iii-study-for-vaccine-to-protect> abgerufen werden.

Intercell AG

EANS-News: Intercell announces initiation in the U.S. of a Phase III study for vaccine to protect children against Japanese Encephalitis

28.12.2009 - 08:26 Uhr, Intercell AG

- » First Phase III trial towards pediatric label extension for IXIARO®/JESPECT® preventing Japanese Encephalitis (JE) in travelers to endemic countries » Important development step towards making IXIARO/JESPECT available to children

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----- Research & Development

Subtitle: - » First Phase III trial towards pediatric label extension for IXIARO®/JESPECT® preventing Japanese Encephalitis (JE) in travelers to endemic countries » Important development step towards making IXIARO/JESPECT available to children

Vienna (Austria), December 28, 2009 (euro adhoc) - Intercell AG today announced the initiation of a pediatric Phase III study for IXIARO/JESPECT in children above 6 months of age travelling from U.S., Europe and Australia to JE-endemic areas. The vaccine is currently licensed as adult vaccine in Europe, Canada, the United States (IXIARO) and Australia (JESPECT).

In the U.S., the vaccine is licensed for those above 17 years of age, and in Europe, Canada and Australia it is licensed for those above 18 years of age. This multi-national study including 100 children will be the first of two Phase III trials in support of the IXIARO/JESPECT label extension for pediatric licensure for children above 2 months of age. The study will investigate safety and immunogenicity of the vaccine.

"We are very pleased about the progress in our pediatric development program for this vaccine. The start of the current Phase III study is a major step towards making our modern cell culture-derived product available also to travelling children and to the children of those serving in the military who are bringing their families to countries with JE-endemic areas", states Thomas Lingelbach, Chief Operating Officer of Intercell AG.

The development program up to licensure for pediatric use of IXIARO/JESPECT has been agreed with the regulatory authorities. A Phase II study conducted in 2007 comprising children aged 1 to 3 years of age by Intercell's partner Biological E. suggested that the vaccine has a comparable immunogenicity and safety profile in young children to that in adults, even if only half of the adult dose is administered.

A second Phase III study will be conducted as a pivotal trial in an endemic region, namely, the Philippines and Malaysia. This multi-center, randomized and controlled study will include 1,859 children of whom 1,401 will receive IXIARO/JESPECT. The study will evaluate the safety profile of the vaccine compared to HAVRIX®720 and Prevnar®. In addition, immunogenicity will be studied in a subgroup of children, and the vaccine dose for ages three to below 12 years will be confirmed.

Following the approval and launch of Intercell's vaccine against Japanese Encephalitis for adult travelers and military personnel in Europe, Canada, the USA and Australia, the further development of the vaccine to protect children travelling to endemic areas from Japanese Encephalitis has been a major goal of the company. Intercell is also working with its partner Biological E. of Hyderabad, India, to make a JE vaccine available in endemic regions.

end of announcement

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