



## **Intercell announces initiation in the U.S. of a Phase III study for vaccine to protect children against Japanese Encephalitis**

- » 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** – 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.



## About Japanese Encephalitis

Japanese Encephalitis (JE) is a deadly infectious disease found mainly in Asia. Approximately 30,000 to 50,000 cases of JE are reported in Asia each year, and the actual number of cases are likely much higher due to underreporting in rural areas. JE is fatal in approximately 30 percent of those who show symptoms and leaves half of survivors with permanent brain damage. As there is no specific treatment for JE, vaccination is the only effective protection for the millions of travelers and military personnel who live in or travel to areas where the virus circulates.

## About Intercell AG

Intercell AG is an innovative biotechnology company that develops novel vaccines for the prevention and treatment of infectious diseases with substantial unmet medical needs. Intercell's vaccine to prevent Japanese Encephalitis is the Company's first product on the market.

The Company's technology platforms include an antigen-discovery system, adjuvants and a novel patch-based delivery system (Vaccine Patch, Vaccine Enhancement Patch). Based on these technologies, Intercell has strategic partnerships with a number of global pharmaceutical companies, including GSK, Novartis, Merck & Co., Inc., Sanofi Pasteur, and Wyeth.

The Company's pipeline of investigational products includes a Travelers' Diarrhea Vaccine Patch (Phase III), a Pseudomonas vaccine candidate (Phase II), a Vaccine Enhancement Patch to prevent Pandemic Influenza in combination with an injected vaccine (Phase II), a vaccine program for S. aureus, which is being developed with Merck & Co., Inc. (Phase II/III), as well as a vaccine candidate for Pneumococcus (Phase I). In addition, three other products focused on infectious diseases are in pre-clinical development.

Intercell is listed on the Vienna stock exchange under the symbol "ICLL" (U.S. level one ADR symbol "INRLY").

For more information, please visit: [www.intercell.com](http://www.intercell.com)

## Contact

### Intercell AG

Lucia Malfent

Global Head Corporate Communications

Campus Vienna Biocenter 3, A-1030 Vienna

P: +43-1-20620-1303

Mail to: [LMalfent@intercell.com](mailto:LMalfent@intercell.com)

*This communication expressly or implicitly contains certain forward-looking statements concerning Intercell AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of Intercell AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Intercell AG is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.*