



## **Intercell announces European approval of new vaccine, IXIARO<sup>®</sup>, to prevent Japanese Encephalitis**

- » European Commission grants marketing authorization for Intercell's IXIARO, the first licensed vaccine against Japanese Encephalitis for travelers and military personnel in Europe
- » This final decision follows the positive opinion from European Committee for Human Medicinal Products (CHMP) in December 2008

**Vienna (Austria), April 2, 2009** – Intercell AG (VSE: ICLL) today announced that its new vaccine to prevent Japanese Encephalitis, IXIARO<sup>®</sup>, has been approved by the European Commission. The approval by the European Union, the first for a vaccine to prevent the disease, provides formal market authorization in all 27 member states as well as Norway and Iceland.

“The European approval of IXIARO marks a crucial milestone in Intercell's evolution as one of the leading independent vaccine development companies with a vaccine marketed,” said Intercell's Chief Executive Officer Gerd Zettlmeissl. “For the first time, both civilians and members of the military across Europe will have access to a safe and effective vaccine against this devastating and endemic disease found throughout Asia, which kills as many as one in three of the people it strikes.”

This decision follows the positive opinion from European Committee for Human Medicinal Products (CHMP) in December 2008. Novartis AG holds marketing and distribution rights for IXIARO, in the United States, Europe, Japan, Korea and certain other markets in Asia and Latin America.

A final assessment by the European COMP (Committee for Orphan Medicinal Products) focused on updated information indicating that the expected potential European vaccine market for IXIARO is significantly higher than initially evaluated, and, therefore, the vaccine will not have an orphan drug designation.

Intercell's product is a purified, inactivated vaccine for active immunization against infections with Japanese Encephalitis virus. The new vaccine is manufactured in Intercell's proprietary manufacturing facility in Scotland and is prepared using tissue culture rather than live organisms.

In addition to the European approval, Intercell's vaccine was also approved by the Australian Therapeutic Goods Administration (TGA) for use in Australia, and the U.S. Food and Drug Administration for the U.S. market.



## **About Japanese Encephalitis**

Japanese Encephalitis is a mosquito-borne infection that strikes 30,000 to 50,000 individuals a year, causing 10,000 to 15,000 deaths (both probably an underestimate due to underreporting and other factors). Up to 50 percent of survivors have persistent neurological sequelae. Japanese Encephalitis is the leading cause of viral neurological disease and disability in Asia and the most important viral encephalitis in Asia. The disease is most common in several developing countries in Asia, including India and China. As there is no specific treatment for JE, health care experts recommend vaccination as the only highly effective protection for the millions of travelers and military personnel who live in or travel to areas where the virus circulates.

## **About IXIARO**

Intercell's novel Japanese Encephalitis vaccine is a purified, inactivated vaccine for active immunization against the Japanese Encephalitis virus. The total development time of this vaccine took more than 10 years. The vaccine was developed under a Collaborative Research and Development Agreement with the Walter Reed Army Institute of Research, a biomedical research laboratory for the U.S. Department of Defense.

Intercell's Phase III trials for the vaccine found that the vaccine demonstrated excellent immunogenicity against Japanese Encephalitis and an overall clinical safety profile similar to placebo, combined with an excellent local tolerability profile. These data were published in *The Lancet* in December 2007:

- » The immunogenicity was comparable to that of the U.S. licensed product, JE-VAX®.
- » Intercell's vaccine demonstrated an overall clinical safety profile similar to placebo.
- » Further, Intercell's Japanese Encephalitis vaccine had a more favorable local tolerability profile in the head-to-head study with JE-VAX®.

## **About Intercell AG**

Intercell AG is an innovative biotechnology company that designs and 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. Based on these technologies, Intercell has strategic partnerships with a number of global pharmaceutical companies, including Novartis, Merck & Co., Inc., Wyeth, Sanofi Pasteur, Kyowa Hakko Kirin and the Statens Serum Institut.

The Company's development pipeline includes Phase II vaccine programs for *Pseudomonas* (in-house development) and *S. aureus*, which is being developed with Merck & Co. Inc. The Company's novel Travelers' Diarrhea vaccine patch will enter Phase III testing in 2009. Intercell is also in clinical trials of a vaccine enhancement patch with injected Pandemic



Influenza vaccines (one shot plus patch). In addition, four other products focused on infectious diseases are in pre-clinical development.

Intercell is listed on the Vienna stock exchange under the symbol "ICLL".

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

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