

Diese Meldung kann unter <http://www.presseportal.de/pm/53037/1321044/euro-adhoc-intercell-ag-other-intercell-receives-chmp-positive-opinion-for-the-approval-of-ixiaro> abgerufen werden.

Intercell AG

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other

Intercell receives CHMP positive opinion for the approval of IXIARO® in Europe - A vaccine against Japanese Encephalitis

15.12.2008 - 15:08 Uhr, Intercell AG

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New

Products

15.12.2008

» IXIARO® receives positive opinion from European Committee for Human Medicinal Products (CHMP) » First licensed vaccine against Japanese Encephalitis for travelers and military personnel to enter markets in Europe » Commercial product launch in the U.S., Europe and Australia expected in early 2009

Vienna, Austria, December 15, 2008 - Intercell AG (VSE: ICLL) today announced that the CHMP of the European Medicines Agency (EMA) has come to a positive opinion on the Marketing Authorisation for IXIARO®, a vaccine against Japanese Encephalitis (JE).

JE is a deadly infectious disease found mainly in Asia. 30-50,000 cases of JE are reported in Asia each year. JE is fatal in approximately 30% of those persons who manifest JE and leaves one-half of survivors with permanent brain damage. As there is no specific treatment for JE, health care experts recommend vaccination as the only protection for the millions of travelers and military personnel who live in or travel to areas where the virus circulates. Consequently the initial target for use of Intercell's vaccine will be adult civilian travelers and military personnel who visit or are deployed to affected countries, including India, China, Southeast and Southwest Asia.

"The CHMP positive opinion is great news for the global health care system as with IXIARO®, European travelers will have access to an efficacious and safe vaccine to protect from the devastating effects of Japanese Encephalitis," said Intercell's Chief Executive Officer, Gerd Zettlmeissl. IXIARO® will be the first vaccine ever licensed in Europe to protect against JE. "It is great news for Intercell as well, as our first product ever IXIARO® will from now on provide the company with significant product sales," adds Zettlmeissl.

Intercell's vaccine is a purified, inactivated product for active immunization against viral infections of Japanese Encephalitis. IXIARO® is manufactured in Intercell's proprietary manufacturing facility in Scotland and is prepared using tissue culture rather than live organisms. Novartis AG holds marketing and distribution rights for Intercell's Japanese Encephalitis vaccine, trade named IXIARO®, in the United States, Europe and certain other markets in Asia and Latin America.

Up to approval the vaccine was tested in a series of clinical trials with around 5000 individuals. The total development time of this vaccine from research to approval took more than 10 years, required a total investment of more than EUR 100 m.

A single Marketing Authorization covering all 27 member states of the European Union as well as Norway and Island will follow as a next step and will allow for the planned market launch in early 2009. This will then also trigger a EUR 10 m milestone payment by Novartis. State control testing by the "Official Medicines Control Laboratories" (Paul Ehrlich Institut, Germany and National Institute for Biological Standards and Control UK) for vaccine lots intended to be supplied into the European markets, will be initiated shortly.

About Japanese Encephalitis

Japanese Encephalitis is a mosquito-borne infection that strikes 30,000 to 50,000 a year, causing 10-15,000 deaths. Up to 50% 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. No treatment is currently available; only vaccination effectively prevents the disease. Though other vaccines have been available in the past, use

of those products has been limited by reports of neurological reactions.

About Intercell's JE vaccine

Intercell's novel JE vaccine is a purified, inactivated vaccine for active immunization against the Japanese Encephalitis virus. With over 3 billion people living in endemic areas, Japanese Encephalitis, a mosquito-borne flaviviral infection, is the leading cause of childhood encephalitis and viral encephalitis in Asia. The vaccine was developed for over 10 years under a Collaborative Research and Development Agreement (CRADA) with the Walter Reed Army Institute of Research (WRAIR).

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. That data was 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 JE vaccine had an excellent local tolerability profile in the head-to-head study with JE-VAX®

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inquiry note:

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WKN: A0D8HW
Index: ATX Prime, ATX
Börsen: Wiener Börse AG / official market

Originaltext:	Intercell AG
ISIN:	AT0000612601
Pressemappe:	http://www.presseportal.de/pm/53037/intercell-ag
Pressemappe als RSS:	http://presseportal.de/rss/pm_53037.rss2