



## **Intercell announces pediatric approval of its Japanese Encephalitis vaccine in Europe**

**Vienna (Austria), February 12, 2013** – Intercell AG (VSE; “ICLL”) announced today that the pediatric indication for IXIARO<sup>®</sup>, a vaccine to protect against Japanese Encephalitis (JE), was granted Marketing Authorisation by the European Medicines Agency (EMA) and the European Commission (EC). The European Commission Decision ratifies the positive opinion from the European Committee for Human Medicinal Products (CHMP) in December 2012. The approval by the European Union provides formal Marketing Authorisation for the pediatric indication of IXIARO<sup>®</sup> in all 27 member states as well as Norway, Liechtenstein and Iceland.

“We are delighted that our JE vaccine has been granted pediatric licensure in Europe, which will now enable travelers of all ages to obtain protection against this disease with a licensed vaccine. The approval of IXIARO<sup>®</sup> for children is based on additional clinical studies that have once more confirmed the favorable safety and immunogenicity profile of the vaccine.”, says Thomas Lingelbach, Chief Executive Officer of Intercell AG.

Intercell submitted applications for pediatric licensure of the JE vaccine to major regulatory agencies in late Q2 2012 based on data from a Phase III clinical study conducted in the Philippines and favorable interim data from a second Phase III trial in EU, US and Australia. In both studies the JE vaccine was shown to be highly immunogenic in children/adolescents aged 2 months to less than 18 years with a safety profile comparable to pediatric vaccines licensed for other diseases.

Following the approval and launch of Intercell's vaccine against Japanese Encephalitis for adult travelers and military personnel in Europe, Switzerland, United States, Canada, Hong Kong, Singapore, Israel (IXIARO<sup>®</sup>) and Australia and New Zealand (JESPECT<sup>®</sup>), the development of a vaccine to protect children traveling to endemic areas from Japanese Encephalitis has been a major goal of the Company.

Intercell's next-generation vaccine to protect travelers against Japanese Encephalitis (JE) has been licensed in more than 30 countries world-wide, and is the Company's first product on the market. Extension of the approved indications to include the pediatric age segment in the EU, allows vaccine to be administered to adults and children aged 2 months and above who travel to, or live in, endemic areas. Intercell and its marketing and distribution partners are committed to introducing the IXIARO<sup>®</sup> product for administration in all approved age groups as soon as possible. Product which is currently available on the market in Europe can be used in accordance with the approved method of administration in all people aged 3 years and above.





In the U.S. the pediatric label extension is currently under review by the FDA.

The vaccine is manufactured by Intercell AG's wholly-owned subsidiary Intercell Biomedical Ltd. at its cGMP facility in Livingston, Scotland.

### **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 is 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. The disease is endemic in Southeast Asia, a region with more than 3 billion inhabitants. Only within 1 month in the year 2005, Japanese Encephalitis killed more than 1,200 children during an epidemic outbreak in Uttar Pradesh, India, and Nepal.

### **About IXIARO®/JESPECT®**

Intercell's Japanese Encephalitis vaccine is a purified, inactivated vaccine for active immunization against the Japanese Encephalitis virus. The total development time of this vaccine was 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 of the U.S. Department of Defense.

Intercell's Phase III trials for the approval of the vaccine in adults found that the vaccine demonstrated excellent immunogenicity against Japanese Encephalitis and an overall clinical safety profile similar to the control arm, 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, then still marketed, U.S. licensed product, JE-VAX®.
- » Intercell's vaccine demonstrated an overall clinical safety profile similar to the control arm.

Further, Intercell's Japanese Encephalitis vaccine had a more favorable local tolerability profile in the head-to-head study with JE-VAX®.

In pediatric studies the JE vaccine showed to be highly immunogenic in children aged 2 months to <18 years with a safety profile comparable to pediatric vaccines licensed for other diseases.

Novartis distributes the vaccine to North America and Europe as well as Hong Kong and Singapore (IXIARO®), whereas bioCSL distributes the vaccine in Australia and New Zealand (JESPECT®). Please refer to the Product / Prescribing information (PI) / Medication Guide approved in your respective countries for complete information including safety about this vaccine and details for reporting adverse events or inadvertent use in pregnant women/nursing mothers.



### **Important Safety Information**

IXIARO® is indicated for active immunization against Japanese encephalitis in adults, adolescents, children and infants aged 2 months and older in EU member states, Norway, Liechtenstein and Iceland. In all other licensed territories, IXIARO®/JESPECT® is indicated for use in persons 18 years of age and above (17 years and above in the USA).

You should not receive this vaccine if you have had an allergic reaction to IXIARO®/JESPECT®. This vaccine contains protamine sulfate, which may cause allergic reactions in some people. Tell your doctor if you have had an allergic reaction to protamine sulfate before you receive this vaccine. After you are vaccinated, tell your doctor if you have any of the following problems because these may be signs of an allergic reaction: difficulty breathing, hoarseness or wheezing, hives, dizziness, weakness, or fast heartbeat.

IXIARO®/JESPECT® may not fully protect everyone who gets the vaccine. IXIARO®/JESPECT® does not protect against encephalitis caused by other viruses/pathogens. IXIARO®/JESPECT® does not protect against other diseases transmitted by mosquitoes.

This vaccine is given in 2 doses. Dose 2 is scheduled 28 days after Dose 1. Make sure you receive both doses. It is very important that you receive the 2nd dose of the vaccine at least 7 days before potential exposure to the virus. If you had been previously vaccinated with IXIARO®/JESPECT®, consult with your doctor if you need a booster dose.

Make sure your doctor knows if you have a weakened immune system or are using medicines that may weaken the immune system. Tell your doctor if you are pregnant.

The most common side effects are headache, muscle pain, and injection site reactions (e.g., pain, swelling, tenderness, redness). Nausea, skin rash, fatigue, flu-like illness, and fever may also occur.

### **About Intercell AG**

Intercell AG is a vaccine-biotechnology company with the clear vision to develop and commercialize novel immunomodulatory biologicals to prevent disease and reduce suffering across the world.

Intercell's vaccine to prevent Japanese Encephalitis (JE) – IXIARO®/JESPECT® – is the Company's first product on the market. This is a next generation vaccine against the most common vaccine-preventable cause of encephalitis in Asia, licensed in more than thirty countries. A comparable vaccine for endemic markets based on Intercell's technology was launched in 2012 by Biological E. Ltd. under the trade name JEEV® in India and is currently under review for WHO prequalification.

The Company's technology base includes novel platforms, such as the patch-based vaccine delivery system and the proprietary human monoclonal antibody discovery system eMAB®, in addition to well-established technologies upon which Intercell has entered into strategic



partnerships with a number of leading pharmaceutical companies, including Novartis, Merck & Co., Inc., and Sanofi.

The Company's pipeline of investigational products includes a development program for the pediatric use of Intercell's JE vaccine IXIARO®/JESPECT® in non-endemic markets. Furthermore, the portfolio comprises different product candidates in clinical trials: a *Pseudomonas aeruginosa* vaccine candidate (Phase II/III), a program that is part of the strategic alliance with Novartis, a vaccine candidate against infections with *C. difficile* (Phase I); and other investigative vaccine programs using the Company's IC31® adjuvant, e.g. in a Tuberculosis vaccine candidate (Phase II).

Intercell has in-house cGMP capability to manufacture both clinical and commercial biologicals at its fully owned site in Livingston, Scotland. The manufacturing site is currently dedicated to the production of the Company's novel Japanese Encephalitis vaccine. It is licensed and operates under a Manufacturing Authorisation granted by the Medicines and Healthcare products Regulatory Agency (MHRA) and it is also registered by the FDA. As such, the facility is subject to routine inspection by the MHRA, FDA and other Competent Authorities in connection with the manufacture, sale and supply of Japanese Encephalitis vaccine (trade name IXIARO®/JESPECT®).

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)

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