



## **Intercell Receives Manufacturer's Licence for Future Commercial Manufacturing of its Vaccine Against Japanese Encephalitis**

- » Successfully passed inspection by the Medicines and Healthcare products Regulatory Agency (MHRA)
- » Intercell receives Manufacturer's Licence for its site in Livingston, Scotland
- » Major milestone in bringing vaccine against Japanese Encephalitis (JE) to the American (US) and European markets

**Vienna (Austria), January 16, 2008** – Intercell AG (VSE: ICLL) announced today that its fully owned manufacturing site in Livingston, Scotland (Intercell Biomedical Ltd.), has been granted the Manufacturer's Licence for the commercial manufacturing of its vaccine against Japanese Encephalitis. The issuance of the license is following a GMP (Good Manufacturing Practice) inspection performed by the Medicines and Healthcare products Regulatory Agency (MHRA).

The Manufacturer's Licence is required to support the Marketing Authorization Application (MAA) process in Europe which is being coordinated by the European Medicines Agency (EMA) and represents the basis for future product release and export to the US.

"The issuance of the Commercial Manufacturer's Licence is a key achievement on Intercell's path to bringing our new investigational Japanese Encephalitis vaccine onto the market and should allow us to produce a sufficient launch stock for product approvals in the respective locations," states Gerd Zettlmeissl, Intercell's Chief Executive Officer.

"Receiving the Manufacturer's Licence validates our ongoing commitment to focus on quality compliance and execution for our future commercial supplies," says Thomas Lingelbach, Intercell's Chief Operating Officer.

Intercell expects the pre-approval inspection by the US FDA (Food and Drug Administration) in support of the US licensure process within the forthcoming months.

### **About Intercell's investigational JE vaccine (IC51)**

Intercell's novel investigational JE vaccine (IC51) 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 JE virus remains virulent in this region and has recently spread to countries not previously affected.



In successfully concluded pivotal Phase III trials, Intercell's IC51 vaccine has demonstrated a favorable safety and immunogenicity profile:

- » The immunogenicity of IC51 was at least as good as the U.S. licensed product, JE-VAX®
- » IC51 demonstrated an overall clinical safety profile similar to placebo
- » Further, IC51 showed an excellent local tolerability profile in this head-to-head study with JE-VAX®

Intercell's novel JE vaccine is produced using tissue culture rather than live organisms and does not contain any stabilizers such as gelatin or preservatives in its formulation.

Novartis will market and distribute Intercell's Japanese Encephalitis virus vaccine in the United States, Europe and certain other markets in Asia and Latin America. CSL is Intercell's marketing and distribution partner in Australia.

#### **About Intercell AG:**

Intercell AG is a growing biotechnology company which focuses on the design and development of novel vaccines for the prevention and treatment of infectious diseases with substantial unmet medical need. The Company develops antigens and adjuvants which are derived from its proprietary technology platforms, and has in-house GMP manufacturing capabilities. Based on these technologies, Intercell has strategic partnerships with a number of global pharmaceutical companies, including Novartis, Merck & Co., Inc., Wyeth, sanofi pasteur, Kirin and the Statens Serum Institut. The Company's leading product, a prophylactic vaccine against Japanese Encephalitis, successfully concluded pivotal Phase III clinical trials in 2006. The Market Authorization Application (MAA) in Europe as well as the Biological License Application (BLA) with the US Food and Drug Administration (FDA) for the use of the vaccine to prevent Japanese encephalitis were submitted in December 2007. The company's broad development pipeline includes a Pseudomonas vaccine in Phase II, a therapeutic vaccine for Hepatitis C in Phase II, partnered vaccines for Tuberculosis (Phase I) and Staphylococcus aureus (Phase II), and five products focused on infectious diseases in preclinical 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)

#### **About Intercell Biomedical Ltd. (Livingston, Scotland)**

In 2004, Intercell acquired a manufacturing plant in Livingston, Scotland, which has enabled the Company to gain in-house GMP manufacturing capabilities for its Japanese encephalitis vaccine and to manufacture the investigational product used in the Phase III clinical trials. With major investments in the last years, the Company has further increased capacities and established a state-of the art, GMP commercial manufacturing facility to support the future supplies of its Japanese encephalitis vaccine. Besides the fully dedicated and further



expandable manufacturing facility, the Livingston site has also separate development and clinical manufacturing capacities.

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