



Intercell initiates regulatory process for its Japanese Encephalitis Vaccine to the U.S. Food and Drug Administration (FDA)

- » Successful pre-BLA meeting with the FDA in September 2006
- » Intercell has now initiated the regulatory process towards a Biologics License Application (BLA) for its Japanese Encephalitis vaccine (IC51)
- » Intercell AG is on track to complete submission in early 2007 with approval expected same year

Vienna (Austria), October 12, 2006 – Intercell AG (VSE, “ICLL”) announced today that it has initiated the regulatory process towards a Biologics License Application (BLA) for its Japanese Encephalitis (JE) vaccine (IC51) to the U.S. Food and Drug Administration (FDA).

This significant event follows a successful pre-BLA meeting held between the FDA and Intercell on September 19, 2006, during which a detailed plan for filing of the BLA was discussed and agreed upon. Initially, full reports of the completed pivotal clinical studies will be submitted to the FDA.

Intercell announced earlier the successful completion of the pivotal immunogenicity and pivotal safety trials of IC51. In these Phase III trials, Intercell’s JE vaccine 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, the local tolerability of IC51 appeared to be more favorable than JE-VAX® in a head-to-head study.

The pivotal Phase III clinical trial program is designed to meet regulatory requirements in the United States, Europe and Australia. Assuming approval of Intercell’s BLA by the regulatory authorities, the first market launch for IC51 is anticipated for 2007.

About Intercell’s investigational JE vaccine (IC51)

Intercell’s novel investigational JE vaccine is a purified, inactivated vaccine for active immunization of adults 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.

In successful concluded pivotal **Phase III trials**, Intercell’s Japanese Encephalitis 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, the local tolerability of IC51 appeared to be more favorable than JE-VAX® in this head-to-head study

Full clinical results of the pivotal immunogenicity trial will be presented at the Annual Meeting of the American Society of Tropical Medicine and Hygiene (ASTMH), November 12-16, 2006 in Atlanta, Georgia, and full clinical results of the pivotal safety trial are planned to be presented at the 10th Conference of the International Society of Travel Medicine, May 20-24, 2007 in Vancouver, Canada.

Intercell's novel JE vaccine, manufactured in the Company's proprietary manufacturing facility in Scotland, is prepared using tissue culture rather than live organisms and, unlike JE-VAX®, does not contain any stabilizers or preservatives in its formulation.

Novartis and Intercell announced on June 13, that the companies had reached an agreement for Novartis to acquire marketing and distribution rights Intercell's Japanese Encephalitis Virus Vaccine in the United States, Europe and certain other markets in Asia and Latin America

About Intercell

Intercell AG is a biotechnology company focused on the research, development, manufacturing and future commercialization of innovative vaccines for the prevention and treatment of infectious diseases, for which there exists a substantial unaddressed medical need. Intercell develops antigens and immunizers (adjuvants), which are derived from its proprietary technology platforms and has in-house GMP manufacturing capability. Intercell has strategic partnerships with a number of global pharmaceutical companies, including Novartis, Wyeth, Sanofi Pasteur S.A., Merck & Co., Inc., Kirin Brewery Co., Ltd. and the Statens Serum Institut. Intercell has a broad development pipeline with a vaccine product candidate for Japanese Encephalitis in Phase III clinical trials, a vaccine product candidate for Hepatitis C in Phase II, partnered vaccine candidates for Tuberculosis and S. aureus, which are in Phase I, and more than five other product candidates focused on infectious diseases in pre-clinical development. Intercell is listed on the Vienna stock exchange under the symbol "ICLL".

For more information, please visit: www.intercell.com **Contact Intercell AG:**

Intercell AG

Katharina Wieser

Head of Corporate Communications

Campus Vienna Biocenter 2, A-1030 Vienna

P: +43-1-20620-303

Mail to: kwieser@intercell.com

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