

FDA approves Intercell's Clinical Development Strategy of Phase III clinical trials for Prophylactic Vaccine against Japanese Encephalitis Virus (IC51)

Vienna, Austria, January 10th, 2005 – Intercell AG today announced that it had a constructive meeting with the US Food and Drug Administration (FDA) regarding the further development of Intercell's IC51 vaccine against the Japanese Encephalitis Virus (JEV). The results of the meeting are:

- FDA allows the project to move directly into Phase III trials
- Intercell will pursue Phase III manufacturing and development work at full speed
- FDA is willing to work with Intercell to achieve a timely and complete BLA (Biologics License Application) submission

Produced on Vero cells, IC51 is a purified, inactivated vaccine for active immunization against the Japanese Encephalitis virus and has successfully concluded Phase II clinical trials. The only currently approved vaccine JE-VAX® in the United States is produced on mouse brain.

During the meeting, the FDA agreed that the Phase II data, in combination with the manufacturing comparability protocol for the final production process, would enable Intercell to move directly into Phase III immunogenicity and safety trials. Intercell will further pursue its manufacturing and development work as planned.

The global, multi-center Phase III study will involve about 800 individuals for a non-inferiority trial in comparison with the JE-VAX® and about 3,000 individuals for a safety trial.

The final production process will take place in Intercell's GMP facility in Livingston, Scotland, which recently received Manufacturing Authorisation for Investigational Medicinal Products (MA(IMP)) from the UK Medicines and Healthcare products Regulatory Agency (MHRA).

Intercell's COO Gerd Zettlmeissl: "We are highly satisfied with the outcome of this constructive meeting with the US FDA. It confirms that our development strategy for IC51 is appropriately planned and underlines our determination to achieve a rapid completion of the late stage clinical trials to launch the vaccine into the US market in 2007."

The target market for IC51 will be the armed forces, tourists and travelers from the United States, the European Union and Australia who travel to the endemic areas. Intercell will handle direct distribution and sales in the United States and plans to enter partnerships in Australia, Europe and Asia.

Phase II results:

In a Phase II head-to-head comparison with JE-VAX®, IC51 was shown to be:

- Less reactogenic - both in frequency and intensity
- More potent - higher antibody levels at all doses studied one month after the immunizations; IC51 also showed high seroconversion rates one month after a single dose
- More convenient - 2 doses versus 3 doses and liquid versus freeze-dried format
- More persistent – higher persistence of antibodies two years after primary immunization

More detailed Phase II results were presented at the 53rd annual meeting of the American Society of Tropical Medicine and Hygiene, Nov 7th – Nov 11th in Miami. For more information please visit: www.intercell.com

About Japanese Encephalitis

The Japanese encephalitis virus was first identified in 1935 in Japan. It is a mosquito-borne flaviviral infection and the leading cause of viral encephalitis. JEV is still a huge public health problem in Southeast Asia and the Western Pacific and the virus is spreading into new areas. Two billion people live in endemic areas and 30.000 to 50.000 cases are reported annually of which approximately 25 % are fatal. . The current vaccine available on international basis is made from infected mouse brains and has considerable side effects. Because of sophisticated production technology required, hypersensitivity and side effects upon vaccination with first generation JEV vaccines, the WHO is encouraging the development of a safe, tolerant and immunogenic second generation Japanese Encephalitis vaccine.

The market potential for a safe and efficient vaccine against JEV is estimated to be up to approximately Euro 250 million.



About Intercell

Intercell is a fast growing biotechnology company with a clear strategy and focus on the design and development of novel vaccines for prophylactic and therapeutic treatment of diseases with substantial unmet needs. The Company's unique position is based on the combination of antigens and immunizers (adjuvants) derived from its proprietary technology platforms and its in-house GMP facilities. Intercell's technology has been endorsed by collaborative agreements with a number of global pharmaceutical companies, including Aventis Pasteur, Merck&Co., Inc., Scigen and the Statens Serum Institut. The Company has a broad development pipeline with a vaccine for Japanese Encephalitis about to enter Phase III, a vaccine for Hepatitis C undergoing Phase II trials, and five products focused on infectious diseases in the pre-clinical phase. To date, Intercell has raised approximately Euro 100 million in external funding from international investors.

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

www.intercell.com

Brunswick

Jon Coles/Wendel Verbeek/
Laure Korenian-Chabert
16 Lincoln's Inn Fields
London EC2A 3ED
United Kingdom

P: +44-(0)20-7404-5959

Mail to: intercell@brunswickgroup.com

This communication expressly or implicitly contains certain forward-looking statements concerning Intercell AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of Intercell AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Intercell AG is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.