



## **Intercell's investigational vaccine against Japanese Encephalitis shows excellent safety and immunogenicity in Phase II trials in children**

- » Japanese Encephalitis (JE) Vaccine meets primary endpoints in Phase II trials in children
- » The results fully support Intercell's development plan for endemic regions and pave the way towards late stage development and licensure – planned for late 2009 / early 2010

**Vienna (Austria), April 15, 2008** – Intercell AG and its partner Biological E. Ltd. (Hyderabad, India) today announced the analysis of Phase II data for its investigational pediatric vaccine against Japanese Encephalitis.

The randomized and controlled study shows an excellent safety and immunogenicity profile amongst children in endemic areas. The study which started in 2007 enrolled 60 healthy children at the age of one to three years.

The seroconversion rate of the test vaccine (given in two doses at days 0 and 28) in the IC51-3mcg dose group ("half adult dose") was 96 % and thus comparable to seroconversion rates observed in adults in former pivotal Phase III clinical trials.

Also the geometric mean titers (GMT of about 200) observed at day 56 after the first vaccination for recipients in the "half adult dose" group were in a similar range to the ones recorded in the pivotal Phase III trials for adults.

The safety profiles of IC51 in children were very favorable and are fully in line with the data obtained from the broad Phase III safety studies in adults.

In summary the data suggest that IC51 in young children (one to three years of age) has a comparable excellent immunogenicity and safety profile as in adults even if only half of the adult dose is applied. This allows Intercell and its partner Biological E. to enter into late stage development towards the licensure of the vaccine for the use in children in India and other parts of South East Asia. Start of Phase III clinical trials in India are planned for end 2008/early 2009.

"These results clearly confirm our straight forward development process and leadership for our Japanese Encephalitis vaccine for children, which are living in endemic areas and are threatened by this terrible disease. We are now even more encouraged to enforce all necessary activities to make our novel product also available to the children in Asia in the fastest possible way.", states Gerd Zettlmeissl, Chief Executive Officer of Intercell AG.

Vijay Kumar Datla, Chairman and Managing Director of Biological E. Ltd added: "The success of this Phase II study is a significant milestone in our program. With these encouraging study results we hope to accelerate the program and make the product available at the earliest for the protection of vulnerable pediatric and adult population living in JE endemic regions."

Besides the approval and launch of Intercell's investigational vaccine against Japanese Encephalitis for adult travelers and military personnel in Europe, USA and Australia, the development of a vaccine to prevent children in endemic areas from Japanese Encephalitis, is a major goal.

### **About Japanese Encephalitis**

Japanese encephalitis is the most important cause of viral encephalitis in Asia. The Japanese encephalitis virus (JEV) is estimated to cause at least 50 000 cases of clinical disease every year, mostly in children younger than 10 years. 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 1200 children during an epidemic outbreak in Uttar Pradesh, India, and Nepal.

### **About Biological E. Ltd**

Over the last 50 years, Biological E. Ltd. (BE) has been a leading vaccine and pharmaceutical company. The company produces a range of critical vaccines and has been an active partner in the National Immunization Program of India. The company is currently commissioning large scale cGMP facilities in order to increase its capacities and product range to offer these vaccines on a global basis. In addition to its current pipeline of combination vaccines that are entering pivotal trials, BE has R&D programs to develop novel vaccines for both vector borne and enteric diseases. The company has entered into a number of strategic collaborations with leading biotech companies and research institutes for basic R&D. Biological E. is a privately held company. Biological E will manufacture Intercell's JE vaccine for the Asian markets and will exclusively market and distribute the product in India, Nepal, Bhutan and Bangladesh.

For more information please visit: [www.biologicale.com](http://www.biologicale.com)

### **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 of 2007. The licensure application to TGA (Therapeutic Goods Administration) in Australia was submitted in February of 2008.

The company's broad development pipeline includes a partnered *S. aureus* vaccine in Phase II, a therapeutic vaccine against Hepatitis C in Phase II, a *Pseudomonas* vaccine in Phase II, a partnered Tuberculosis vaccine (Phase I/II), and five products focused on infectious diseases in preclinical development.

Intercell is listed on the Vienna Stock Exchange under the symbol "ICLL".



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