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

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Research & Development

15.04.2008

» 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 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

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inquiry note:

Further

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