



Intercell making strides towards imminent approval of its Japanese Encephalitis vaccine in the United States – Approvals in United States, Europe and Australia remain on track for 2008

- » Intercell receives positive feedback from the US Food and Drug Administration (FDA) towards earliest possible product approval
- » Discussion on Japanese Encephalitis vaccines is expected to take place at the meeting of the Advisory Committee for Immunization Practices (ACIP) on October 22
- » The European centralized procedure approval process also is advancing according to plan targeting a positive opinion from the Committee for Medical Products for Human Use (CHMP) by end 2008
- » In Australia, following Therapeutic Goods Administration's (TGA) earlier decision to accelerate the approval process, a positive approval decision is expected in 2008

Vienna (Austria), October 20, 2008 – Following the positive feedback from the FDA, Intercell announced today an update on the regulatory approval processes for its Japanese Encephalitis vaccine in the United States, Europe and Australia.

In the US, Intercell has concluded all submissions requested by the FDA towards licensure. The remaining final formal alignment steps on Product Insert leaflet and Product Release protocol have been initiated. Intercell and the FDA are now jointly working towards the product approval, which should follow as soon as possible. Given this positive and encouraging feedback from the authority, Intercell has focused its manufacturing efforts on a timely product delivery to the US military still in 2008 and to its distribution partners Novartis and CSL Limited.

Furthermore, Intercell looks forward to the forthcoming ACIP discussion on Japanese Encephalitis vaccines scheduled for October 22, 2008. ACIP is the leading vaccine policy-making group in the United States.

For the European Marketing Authorization Application (MAA) Intercell expects to conclude its application submission process by responding to the final list of outstanding issues from the EMEA (European Medicines Agency) within the next few weeks. This plan has been agreed upon with the European authorities and exactly follows the roadmap towards a positive CHMP opinion expected by end of year 2008.

Intercell has received an evaluation report by the licensing authority (TGA) in Australia and plans to conclude all supplementary submissions in the very near future. Intercell is looking towards the next possible advisory meeting and is expecting an approval decision in Australia also before the end of the year.



"We view the recent regulatory feedback from the FDA as extremely positive. It is an outstanding achievement for our company to successfully advance parallel regulatory processes in all key markets for travellers and military personnel", states Gerd Zettlmeissl, Chief Executive Officer of Intercell AG. "Based on the important progress made recently we are very confident that we will obtain approval for our Japanese Encephalitis vaccine in the United States, Europe and Australia during 2008. Although we have not yet received the US approval at this point the current regulatory progress fully supports our strategy and all of our commercial plans."

Novartis AG holds marketing and distribution rights for Intercell's Japanese Encephalitis vaccine, trade named IXIARO®, in the United States, Europe and certain other markets in Asia and Latin America.

"We are pleased with the progress of Intercell's international licensing processes for a vaccine for such a significant unmet medical need and have aligned our efforts to prepare for successful product launches for the US and European traveller markets starting in early 2009", states Joerg Reinhardt, Chief Executive Officer of Novartis Vaccines and Diagnostics.

About Japanese Encephalitis

Japanese Encephalitis is a mosquito-borne infection that strikes more than 50,000 people per year, causing more than 15,000 deaths. An infection with Japanese Encephalitis is usually severe, resulting in serious neurological effects in as many as half of the cases and a fatal outcome in about 25 percent of all cases. No treatment is currently available; only vaccination effectively prevents the disease. The disease is most common in several developing countries in Asia and has expanded into new areas. Most affected are residents in rural areas, particularly children. In addition, the virus is a consistent threat to millions of international travelers and military personnel who visit or are deployed to these Asian nations.

Intercell's Phase III trials for IXIARO® found that the vaccine demonstrated excellent immunogenicity against Japanese Encephalitis and an overall clinical safety profile similar to placebo combined with an excellent local tolerability profile. That data was published in The Lancet in December 2007.

About Intercell AG

Intercell AG is a growing biotechnology company that designs and develops novel vaccines for the prevention and treatment of infectious diseases with substantial unmet medical needs. The Company's technology platforms include an antigen-discovery system, two proprietary adjuvants and a novel patch-based delivery system. 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 development pipeline includes Phase II vaccine programs for Pseudomonas (in-house development) and S. aureus, which is being developed with Merck & Co. Inc. The Company's novel Travelers' Diarrhea vaccine patch will enter Phase III testing in 2009.



Intercell is also in clinical trials of a vaccine enhancement patch with injected pandemic influenza vaccines (one shot plus patch). In addition, five other products focused on infectious diseases are in preclinical development.

Intercell is listed on the Vienna stock exchange under the symbol "ICLL".

For more information, please visit: www.intercell.com

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