

Intercell AG

euro adhoc: Intercell AG

other

Intercell Submits Marketing Authorization

Application (MAA) to EMEA for Licensure of Japanese Encephalitis Vaccine

06.12.2007 - 17:55 Uhr, Intercell AG

Disclosure announcement transmitted by euro adhoc. The issuer is responsible
for the content of this announcement.

Information Company

06.12.2007

» Intercell submitted MAA for its lead product, a vaccine against Japanese encephalitis »
Product is intended to be licensed through centralized regulatory procedure in Europe »
Company expects positive CHMP opinion in 2008

Vienna (Austria), December 6, 2007 - Intercell AG (VSE: ICLL) announced the regulatory submission of the MAA (Marketing Authorization Application) today for its lead product, a vaccine against Japanese encephalitis (JE). After successful Phase III clinical trials performed in Europe, the United States and Australia, the new JE vaccine is intended to be licensed through the centralised regulatory procedure by the EMEA (European Medicines Agency).

"It is a major achievement that we have been able to manage Intercell's first MAA submission according to our stated business plans. Furthermore, we are on track for filing a license application for our JE vaccine in the United States later this month. We are encouraged and committed to further delivering on the next steps towards product licensure and commercialization in the U.S., Europe, and elsewhere", stated Thomas Lingelbach, Intercell's Chief Operating Officer.

Subject to EMEA's validation of the submission, a review by the rapporteurs (Germany) and co-rapporteurs (Norway) will be initiated and the Company is expecting a positive opinion by the Committee for Medicinal Products for Human Use (CHMP) in 2008.

About Intercell's investigational JE vaccine (IC51)

Intercell's novel investigational JE vaccine (IC51) is a purified, inactivated vaccine for active immunization 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. The JE virus remains virulent in this region and has recently spread to countries not previously affected. In successfully concluded pivotal Phase III non-inferiority trials, Intercell's IC51 vaccine has demonstrated a favorable safety and immunogenicity profile:

» The immunogenicity of IC51 was comparable to that of the U.S. licensed product, JE-VAX®
» IC51 demonstrated an overall clinical safety profile similar to placebo » Furthermore, IC51 showed an excellent local tolerability profile in this head-to-head study with JE-VAX®

Intercell's novel investigational JE vaccine, manufactured at the Company's proprietary GMP (Good Manufacturing Practice) manufacturing facility in Scotland, is prepared using tissue culture rather than live organisms and does not contain any stabilizers such as gelatin or preservatives in its formulation.

On June 13, 2006, Novartis and Intercell announced, that the companies had reached an agreement for Novartis to acquire marketing and distribution rights for Intercell's Japanese encephalitis virus vaccine in the United States, Europe and certain other markets in Asia and Latin America.

About Intercell Biomedical Ltd.

In 2004, Intercell acquired a manufacturing plant in Livingston, Scotland, which has enabled the Company to gain in-house GMP manufacturing capabilities for its Japanese encephalitis

vaccine and to manufacture the investigational product used in the Phase III clinical trials. With major investments throughout the last years, the Company has further increased its capacities and has established a state-of the art, GMP commercial manufacturing facility to support the future supplies of its Japanese encephalitis vaccine. Besides the manufacturing facility, which is fully dedicated to these studies and still has the potential for further expansion, the Livingston site also has separate development and clinical manufacturing capacities. With more than 70 employees, the organization operates under a Manufacturing License from the MHRA (Medicines and Healthcare products Regulatory Agency) for Investigational Medicinal Products (IMP, Investigational Medicinal Products) and is in the process of becoming for commercial manufacturing.

end of announcement

euro adhoc 06.12.2007 17:20:00

inquiry note:

Further

Intercell AG
Lucia Malfent
Head of Communications
Tel. +43 1 20620-303
lmalfent@intercell.com

Branche: Biotechnology
ISIN: AT0000612601
WKN: A0D8HW
Börsen: Wiener Börse AG / official market

Originaltext:

Intercell AG

ISIN:

AT0000612601

Pressemappe:

<http://www.presseportal.de/pm/53037/intercell-ag>

Pressemappe als RSS:

http://presseportal.de/rss/pm_53037.rss2