Intercell provides update on ongoing Phase II vaccine studies

» Pseudomonas vaccine: Study in intensive care patients to investigate immunogenicity and safety of a *Pseudomonas aeruginosa* vaccine and to assess *Pseudomonas* infection rates - Interim results from the study confirms good safety and immunogenicity of the vaccine

» Pandemic Influenza: Intercell originally anticipated it would have data available at the end of the year, but due to data processing not yet completed, data will only be available at the beginning of next year

Vienna (Austria), December 16, 2009 – Intercell AG (VSE; "ICLL") today announced that interim data from a Phase II clinical trial investigating the company's vaccine candidate for the prevention of infections with the bacterium *Pseudomonas aeruginosa* are available. Intercell's vaccine is a recombinant subunit vaccine consisting of two outer membrane proteins of *Pseudomonas aeruginosa.*

In the Phase II clinical trial, mechanically ventilated intensive care patients are vaccinated with Intercell's prophylactic *Pseudomonas aeruginos*a vaccine. These patients are at a particularly high risk of acquiring severe and often life-threatening forms of *Pseudomonas aeruginosa* infections, such as ventilator-associated Pneumonia, Sepsis or soft tissue infection. Two different dosages of alum-adjuvanted vaccine and one formulation without adjuvant are used in the placebo-controlled trial.

The interim analysis from 225 out of 400 total patients to be vaccinated in this study has shown good safety and tolerability of the vaccine. In addition, robust immunogenicity by antibody induction which were assessed by standard and avidity IgG ELISA and functional opsonization assays could be shown. Functional antibodies are expected to be the major protective mechanism against *Pseudomonas aeruginos*a infections. Immune responses and safety data observed in intensive care patients appear largely comparable to results from a preceding Phase I trial in healthy volunteers. Based on these interim data an independent Safety Board recommended the continuation of the study. Meanwhile, the trial is fully enrolled, having achieved recruitment of 400 patients in more than 40 intensive care units in nine countries in Europe and Latin America.

"We are pleased with the state of the clinical conduct although the interim data are not yet decisive. Intercell's approach to develop vaccines against the major causes of nosocomial infections has the clear potential to become the unique strategic solution for a dramatically increasing medical need," comments Thomas Lingelbach, COO of Intercell AG.

Study details

As another objective, the current Phase II trial investigates the feasibility of performing pivotal efficacy studies in this target population. The interim analysis confirms the anticipated number of *Pseudomonas aeruginos*a infections; in total 73/225 patients tested positive for

*Pseudomonas aeruginos*a at any point in time, 23/225 fulfilled the secondary endpoint definitions of invasive disease (Bacteremia, Pneumonia). This observed rate of ~10% is well within expectations, as only study sites with estimated infection rates of 10-25% were selected for this trial. These results confirm the development strategy for Intercell's *Pseudomonas aeruginos*a vaccine and suggest feasibility of the pivotal assessment of vaccine efficacy in future Phase III trials.

However, no conclusions concerning pilot efficacy can yet be drawn at this stage with regards to a meaningful reduction of infections in the different study groups. This assessment will only be concluded at the point of the final data analysis of all 400 patients in the study.

About Pseudomonas aeruginosa

Pseudomonas aeruginosa is one of the leading causes of nosocomial infections, which are infections that patients acquire during the course of receiving treatment for other conditions. Hospital-acquired infections caused by bacteria are one of the major causes of death and serious illness.

Of the 2 million nosocomial infections in the U.S. per year, 10% are caused by *Pseudomonas aeruginosa.* The bacterium is the number 1 cause of ventilator-associated Pneumonia, the number 2 cause of hospital-acquired Pneumonia, and the number 4 cause of surgical site infections.

Pseudomonas aeruginosa causes the most severe and life-threatening infections with a mortality rate of 50% in particular regarding intensive care patients, severe burns patients, cancer and transplant patients who are immunosuppressed. Infections caused by *Pseudomonas aeruginosa* are often difficult to treat because of the increasing antibiotic resistance of these bacteria indicating the high medical need for additional treatments or preventive measures.

Currently, no vaccine against *Pseudomonas aeruginosa* is available.

About Phase II data for Intercell´s investigational Pandemic Influenza Vaccine Patch

The clinical trial is investigating Intercell's Vaccine Enhancement (VE) Patch in combination with an injectable H5N1 Pandemic Influenza vaccine and enrolled 500 subjects in the USA. The study, as part of Intercell's overall PanFlu program, is fully funded by the U.S. Department of Health and Human Services (HHS).

Intercell originally anticipated it would have data available at the end of the year, but due to data processing not yet completed, data will only be available at the beginning of next year.

Intercell believes that its VE Patch, when applied in conjunction with an injectable vaccine has the potential for the development of improved vaccine products. Preclinical studies with different vaccines and the Phase I clinical study results using the VE Patch with an injectable H5N1 Influenza vaccine suggest that this strategy may be used for other injectable vaccines which are already approved or in development where improved immunogenicity, decreased antigen doses, or fewer immunization visits are desired.

About Intercell AG

Intercell AG is an innovative biotechnology company that develops novel vaccines for the prevention and treatment of infectious diseases with substantial unmet medical needs. Intercell's vaccine to prevent Japanese Encephalitis is the Company's first product on the market.

The Company's technology platforms include an antigen-discovery system, adjuvants and a novel patch-based delivery system (Vaccine Patch, Vaccine Enhancement Patch). Based on these technologies, Intercell has strategic partnerships with a number of global pharmaceutical companies, including GSK, Novartis, Merck & Co., Inc., Sanofi Pasteur, and Wyeth.

The Company's pipeline of investigational products includes a Travelers' Diarrhea Vaccine Patch (Phase III), a Pseudomonas vaccine candidate (Phase II), a Vaccine Enhancement Patch to prevent Pandemic Influenza in combination with an injected vaccine (Phase II), a vaccine program for S. aureus, which is being developed with Merck & Co., Inc. (Phase II/III), as well as a vaccine candidate for Pneumococcus (Phase I). In addition, three other products focused on infectious diseases are in pre-clinical development.

Intercell is listed on the Vienna Stock Exchange under the symbol "ICLL" (U.S. level one ADR symbol "INRLY").

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

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