



## **Intercell announces next steps of development for Pseudomonas vaccine**

*Vienna (Austria), April 1, 2011* – Today Intercell AG (VSE: ICLL) announced that it has agreed with Novartis to advance Intercell's investigational *Pseudomonas aeruginosa* vaccine into a confirmatory clinical efficacy trial in ventilated ICU (Intensive Care Unit) patients. The planned double blind study is powered to show a clinically meaningful and statistically significant reduction in overall mortality between the vaccine and control group and envisages enrolling about 800 subjects. The study is subject to final regulatory concurrence and its start is planned for first half of 2012. Intercell will execute the trial and the costs will be shared with Novartis.

Intercell's *Pseudomonas aeruginosa* vaccine program is one of the development programs under the strategic alliance between Intercell and Novartis. Next steps for the program will be decided based upon data from the planned efficacy trial, taking into consideration the Novartis option rights and the Intercell right to choose either profit-sharing or to receive milestones and royalties.

"Pseudomonas infections are a major cause of mortality in artificially ventilated ICU patients. Our Phase II data showed a statistically significant improved survival of patients vaccinated and we are happy that we will together with Novartis move the program forward. This further strongly underlines our leading position to develop vaccines against hospital acquired infections, one of the major medical problems in global societies", states Gerd Zettlmeissl, Chief Executive Officer of Intercell.

The trial is expected to be conducted in various countries, predominantly in the EU, involving up to 50 study sites. Two study groups, both receiving standard of care in addition to vaccine or placebo, will be compared. The subjects in the vaccine group which will comprise about 400 ventilated ICU patients will be vaccinated twice within a 7-day interval with the non-adjuvanted product formulation that was found to most impact observed survival. Primary endpoint of the trial will be mortality at day 28 after first vaccination in both study groups. Secondary objectives are to investigate *Pseudomonas aeruginosa* infections, infection-related mortality as well as immune response to the vaccine candidate and its safety and tolerability.

### **About Intercell's Pseudomonas program**

Intercell's investigational vaccine is a recombinant subunit vaccine consisting of two outer membrane proteins of *Pseudomonas aeruginosa* (OprF and OprI). These outer membrane proteins have been shown to be disease relevant targets in numerous preclinical and several early clinical trials.

In a previous randomized, placebo-controlled Phase II clinical trial a dose and formulation finding in the target population of about 400 ventilated ICU patients was performed by testing three different doses and formulations of the vaccine candidate.



The primary endpoints of this study – vaccine safety and immunogenicity - were met in that all vaccine groups showed high vaccine seroconversion rates (65%-81%, 14 days after first vaccination) with a well tolerated safety profile

Secondary immunogenicity endpoints were also met in this study, including measurement of functional antibody activity by opsonophagocytosis assay

Among clinical secondary endpoints a lower mortality rate was observed in all three vaccine groups as compared to the control group. The reduction in mortality reached statistical significance for the non-adjuvanted vaccine formulation (21.7% day 28 mortality in the not-adjuvanted vaccine candidate group compared to 40.0% day 28-mortality in the placebo group) which has been selected as the lead candidate for further development.

In 2007, Intercell and Novartis announced a major strategic alliance to accelerate innovation in vaccines development in infectious diseases. The partnership is centered around the shared vision of science in vaccines research, development and commercialization. Beside the use of Intercell's adjuvant technology (IC31<sup>®</sup>) in selected vaccines it focuses on the development of vaccine products for which upon Novartis' opt in Intercell has the right at its election either to profit-share with Novartis or to receive potential milestones and royalties tied to sales-performance.

### **About Pseudomonas**

*Pseudomonas aeruginosa* is one of the leading causes of nosocomial infections, which are infections acquired or occurring during the course of hospitalization for other conditions.

Nosocomial infections are becoming more and more a prominent problem as patients admitted to hospitals are on the average older, have underlying chronic illnesses, may have reduced immunocompetence and are increasingly compromised by antibiotic resistant bacteria circulating in hospitals across the world.

Of the 2 million nosocomial infections in the U.S. alone 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.

In particular intensive care patients, severe burns patients, cancer and transplant patients who are immunosuppressed, *Pseudomonas aeruginosa* causes the most severe and life threatening infections with a mortality rate of up to 50%.

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



## **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 platform includes an antigen-discovery system and human anti-infective monoclonal antibody discovery system, adjuvants and a novel patch-based delivery system (Vaccine Patch, Vaccine Enhancement Patch). Based on these technologies, Intercell has strategic partnerships, including with a number of pharmaceutical companies, with GSK, Novartis, Merck & Co., Inc., sanofi-aventis, and Romark.

The Company's pipeline of investigational products includes a *Pseudomonas aeruginosa* vaccine candidate (Phase II), a vaccine to prevent Pandemic Influenza combining our Vaccine Enhancement Patch with an injected vaccine (Phase I/II), a vaccine program for *S. aureus*, which is being developed with Merck & Co., Inc. (Phase II/III), a vaccine candidate for *Pneumococcus* (Phase I) as well as a combination treatment approach for Hepatitis C (Phase II). A vaccine candidate against infections with *C. difficile* entered Phase I clinical trials in 2010. In addition, further 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](http://www.intercell.com)

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