Intercell starts a Phase I clinical trial for a new vaccine to prevent *Clostridium difficile* infections

» After successful pre-clinical trials, Intercell is progressing its vaccine candidate against *Clostridium difficile*, the major cause of nosocomial diarrhea, into the clinical development stage

» Initiation of a first-in-man Phase I clinical trial in healthy subjects

» Study aims to obtain safety and immunogenicity data - initial results expected in Q3 2011

Vienna (Austria), December 22, 2010 – Intercell AG (VSE: ICLL) today announced that a Phase I clinical trial with the company's vaccine candidate IC84 to prevent disease caused by the bacterium *Clostridium difficile (C. difficile)* has started. The pathogen is one of the main causes of nosocomial diarrhea.

Intercell's vaccine candidate is a recombinant protein vaccine consisting of two truncated toxins A and B from *Clostridium difficile*. The toxins are known to be disease-causing and anti-toxin immunity can be protective. The vaccine candidate will be tested with or without the adjuvant aluminum hydroxide.

This Phase I trial is a first-in-man study to obtain safety and immunogenicity data in a small population of healthy adults aged 18-65 years in the first part of the study as well as from healthy elderly subjects above 65 years of age in a second part of the study, the latter age group representing the main target population for a *Clostridium difficile* vaccine. 60 healthy adults and up to 100 elderly subjects will be enrolled in this open-label study. Three different alum-adjuvanted vaccine concentrations will be tested; two of the three vaccine concentrations will also be tested without adjuvant.

"The initiation of this clinical Phase I trial is an important step to further strengthen Intercell's leading position in the development of vaccines against hospital-acquired infections", commented Intercell's COO, Thomas Lingelbach.

There is no vaccine available against *Clostridium difficile*, which represents the leading cause of nosocomial diarrhea in the U.S. and EU and is an increasing burden to the health care system. The disease affects in particular elderly patients with prolonged antibiotic treatment and patients with underlying co-morbidities or immunocompromising conditions. Antibiotic treatment is the current standard of care of *Clostridium difficile*-associated disease but has its limitations due to increasing treatment failures attributable to antibiotic resistance and disease relapse in up to 30% of patients after discontinuation of the treatment.

Potential indications for a *Clostridium difficile* vaccine include community prophylaxis for the elderly, prophylaxis in hospitalized patients with particular risk factors for *Clostridium difficile*-associated disease and the prevention of relapsing disease.

About *Clostridium difficile* infection

C. difficile is an anaerobic spore-forming bacterium that causes diarrhea and more serious intestinal conditions such as colitis. *C. difficile* is shed in faeces and any surface, device, or material that becomes contaminated with faeces may serve as a reservoir for the *C. difficile* spores. When the natural microbial flora of the gut is disturbed (e.g. as a result of antibiotic treatment) and a patient gets in contact with *C. difficile* spores - this can result in a broad range of gastrointestinal symptoms. The symptoms may include diarrhea, cramping, dehydration, fever, nausea and vomiting. In advanced stages it can cause bloody diarrhea and severe inflammation of the gut. *C. difficile* spores are transferred to patients mainly via the hands of healthcare personnel who have touched a contaminated surface or item.

C. difficile rarely causes infections in healthy persons but is a significant threat for patients with gastrointestinal surgery, or for subjects in healthcare settings or with immunocompromising conditions.

Currently, no vaccine against *C. difficile* exists, and antibiotic treatment of the established disease has significant limitations. The incidence of nosocomial infections is steadily increasing due to the growing number of medical interventions and antibiotic resistance. Intercell aims at developing a vaccine for the prevention of recurring *C. difficile* Diarrhea, for hospital prophylaxis, and eventually for community-wide prophylaxis on an age- and risk-based vaccination strategy.

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 with a number of global pharmaceutical companies, including 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 has 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").

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