



Product Development Update: Intercell starts Phase II clinical trial for *Pseudomonas aeruginosa* vaccine and FDA approval of IXIARO® expected in early 2009

- » Initiation of a Phase II clinical trial in mechanically ventilated intensive care patients – Study aims to investigate immunogenicity and safety in intensive care patients and to assess *Pseudomonas aeruginosa* infection rates – Initial results expected in H2 2009
- » After recently achieving positive recommendations in EU and Australia, U.S. approval of Japanese Encephalitis vaccine expected to move into early 2009 – No impact on product launch plans expected

Vienna (Austria), December 29, 2008 – Intercell AG (VSE: "ICLL") today announced that the Phase II clinical trial with the company's vaccine candidate to prevent infections with the bacterium *Pseudomonas aeruginosa* is starting. Intercell's vaccine (IC43) 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, who are at particular high risk of acquiring severe and often life-threatening forms of *Pseudomonas aeruginosa* infections, such as ventilator-associated pneumonia, sepsis or soft tissue infection, will be vaccinated with Intercell's prophylactic *Pseudomonas aeruginosa* vaccine. Two different dosages will be used in the trial. The dosages and vaccination schedule have been identified in a Phase I study initiated earlier this year.

For the current Phase II clinical trial, about 450 patients will be enrolled in more than 50 intensive care units in 11 countries in Europe and Latin America. The study aims to show induction of protective antibody responses against *Pseudomonas aeruginosa*. Antibodies are known to be the "primary line of defense" of our immune system against the intruding bacteria and are therefore the targeted immune response to be measured in the trial. Additionally, the patients will be followed-up for infections caused by *Pseudomonas aeruginosa*, including pneumonia, sepsis, wound infections, urinary tract infections or tracheobronchitis. The overall benefit and quality of life will be assessed by parameters such as length of ICU and hospital stay or number of antibiotic-free days.

"The initiation of this Phase II trial strengthens Intercell's leading position in the field of hospital acquired infections. Intercell's approach to develop vaccines and antibodies 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, Chief Operating Officer of Intercell AG.

In addition to the in-house development of the *Pseudomonas* vaccine, Merck & Co. Inc., together with Intercell develops a vaccine against *S. aureus* infections, which is currently being tested in extensive Phase II clinical trials.





Update on IXIARO® – vaccine candidate to prevent Japanese Encephalitis

Intercell also informed today that despite best collaborative efforts, it does not expect the U.S. Food and Drug Administration (FDA) to complete all administrative steps of the application for IXIARO®, a vaccine for the prevention of Japanese Encephalitis, by the Company's target date of December 31, 2008 and now is looking forward to a U.S. approval in early 2009.

"After our recent excellent achievement obtaining both, the positive opinion in Europe and the recommendation for approval in Australia, we have been in a constant and very productive interaction with the FDA to finalize the license application as quickly as possible," said Intercell's Chief Executive Officer, Gerd Zettlmeissl. "Although our year end target date for approval in the U.S. will be missed we are very confident that we will be able to obtain approval in time to provide this important vaccine to U.S. travelers and military personnel according to our original timelines."

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.

Nosocomial infections are becoming more and more a prominent problem as patients admitted to hospitals are on the average older, multimorbid, 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.

Particularly in 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 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 a growing biotechnology company that designs and 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, 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, Kyowa Hakko 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, four other products focused on infectious diseases are in pre-clinical development.

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

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

Contact Intercell AG

Intercell AG

Lucia Malfent

Head of Corporate Communications

Campus Vienna Biocenter 3, A-1030 Vienna

P: +43-1-20620-1303

Mail to: LMalfent@intercell.com

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