



## **Intercell completes Phase I clinical trial for an improved seasonal Influenza vaccine formulated with IC31®**

- » Intercell's adjuvant IC31® demonstrates very good safety and tolerability profile in first Phase I trial in Flu
- » Seroconversion and seroprotection rates support further clinical development
- » Intercell's strategic Flu partner Novartis to include IC31® in further clinical trials

*Vienna (Austria), February 27, 2008* – Intercell AG (VSE: ICLL) today announced the completion of Phase I clinical trials of the company's adjuvant IC31® in combination with the seasonal, trivalent influenza vaccine Agrippal® from Novartis.

In this randomized, controlled Phase I trial, 72 individuals received one shot of either Agrippal®, or Agrippal® combined with one of two different concentrations of IC31®. All study subjects were healthy, adult volunteers, with an average age of approximately 31 years. The majority of participants had pre-existing immune responses against influenza strains prior to the trial. Subjects were followed for general safety and local tolerability. Vaccine specific immune responses were analyzed 10 and 21 days after the vaccination. The study was conducted at Vienna Medical University, Department of Clinical Pharmacology.

The IC31® adjuvanted vaccine showed - even in the highest IC31® dose group - an excellent safety and tolerability profile, which was comparable to the non-adjuvanted standard vaccine.

Furthermore in all study groups vaccination with the test vaccine led to the induction of virus specific T-cells and protective levels of antibody responses against the three included influenza strains.

"We are excited about the excellent safety and tolerability profile of our IC31® in combination with seasonal influenza antigens in humans", states Gerd Zettlmeissl, Chief Executive Officer of Intercell. "This result in combination with the outstanding immunogenicity data in immuno-compromised animals has paved the way towards the development of improved Flu vaccines."

IC31® has potential as adjuvant for improved influenza vaccines. Novartis will include IC31® in its further clinical development program.

More influenza vaccines are needed with superior immune-response and excellent cross-protection against drifted influenza viruses in the elderly, the age group with the greatest number of death from the annual influenza outbreaks.

As part of the agreement between Novartis and Intercell, signed in July 2007, Novartis has an exclusive license for development of Intercell's IC31® adjuvant in novel influenza vaccines with milestones for Intercell of up to approximately EUR 100 m during the development period and double-digit royalty rates tied to sales performance.



### **About IC31®**

Vaccines, based on antigens alone, are not sufficient to provide full protection. Adjuvants are needed to educate the immune system to recognize and eliminate the pathogens efficiently.

IC31® is an adjuvant that induces T-cell and B-cell responses by using a unique synthetic formulation which combines the immunostimulating properties of an anti-microbial peptide, KLK, and an immunostimulatory oligodeoxynucleotide, ODN1a. The two component solution can be simply mixed with antigens; no conjugation is required.

Intercell currently uses IC31® in collaborations with a number of global vaccine companies and biotech companies. These collaborations include amongst others the development of a tuberculosis vaccine in Phase I clinical trials, which has been partnered with the Danish Statens Serum Institut and Sanofi Pasteur.

### **About Influenza**

The flu is a contagious respiratory illness caused by influenza viruses. The infection usually lasts for about a week. It is characterized by sudden onset of high fever, myalgia, headache and severe malaise, non-productive cough, sore throat, and rhinitis. From 1918 to 1919, the "Spanish Flu" killed more people in the world-wide pandemic than did the First World War.

Influenza viruses cause disease among all age groups. Rates of infection are highest among children, but rates of serious illness and death are highest among persons aged >65 years and children aged <2 years. Influenza rapidly spreads around the world in seasonal epidemics and imposes a considerable economic burden in the form of hospital and other health care costs and lost productivity.

In annual influenza epidemics 5-15% of the population are affected with upper respiratory tract infections. Hospitalization and deaths mainly occur in high-risk groups. Although difficult to assess, these annual epidemics are thought to result in between three and five million cases of severe illness and between 250 000 and 500 000 deaths every year around the world.

Vaccination is the principal measure for preventing influenza and reducing the impact of epidemics. The currently available, mostly not adjuvanted vaccine products have a suboptimal efficacy profile, especially in the population groups with the highest disease burden (elderly and infants). Furthermore, these vaccines only offer limited cross-protection against other influenza strains, with no or low T-cell responses. Due to these limitations, novel vaccines with improved efficacy and T-cell immunity are needed.

### **About Novartis' adjuvanted Influenza vaccine programs**

Novartis currently is the only vaccine manufacturer offering an adjuvanted seasonal influenza vaccine, with more than 30 million doses administered over the past 10 years. FLUAD, when compared to currently available influenza vaccines, induced a higher level of immune response, superior clinical effectiveness and protection against a broader range of influenza strains in vulnerable populations, at higher risk of post-influenza complications.



### **About Intercell AG:**

Intercell AG is a growing biotechnology company which focuses on the design and development of novel vaccines for the prevention and treatment of infectious diseases with substantial unmet medical need. The Company develops antigens and adjuvants which are derived from its proprietary technology platforms, and has in-house GMP manufacturing capabilities. Based on these technologies, Intercell has strategic partnerships with a number of global pharmaceutical companies, including Novartis, Merck & Co., Inc., Wyeth, Sanofi Pasteur, Kirin and the Statens Serum Institut.

The Company's leading product, a prophylactic vaccine against Japanese Encephalitis, successfully concluded pivotal Phase III clinical trials in 2006. The Market Authorization Application (MAA) in Europe as well as the Biological License Application (BLA) with the US Food and Drug Administration (FDA) for the use of the vaccine to prevent Japanese encephalitis were submitted in December 2007. The company's broad development pipeline includes a Pseudomonas vaccine in Phase II, a therapeutic vaccine for Hepatitis C in Phase II, partnered vaccines for Tuberculosis (Phase I) and Staphylococcus aureus (Phase II), and five products focused on infectious diseases in preclinical development.

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

For more information please visit: [www.intercell.com](http://www.intercell.com)

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