



## **Intercell reports Phase II Study Results of its Vaccine Enhancement Patch for Pandemic Influenza**

*Intercell intends to proceed with clinical studies*

**Vienna (Austria)/Gaithersburg (USA), July 2, 2010** – Intercell AG (VSE: ICLL) today announced the results of a Phase II clinical trial of its investigational Vaccine Enhancement Patch (VEP) system for avian H5N1 influenza. In this development program, Intercell is working under a contract with the U.S. Department of Health and Human Services (HHS) to develop a dose-sparing approach with potential for a single dose immunization against pandemic influenza that combines a H5N1 vaccine with Intercell's LT adjuvant patch.

Following encouraging pre-clinical and clinical Phase I proof-of-concept trials conducted under this HHS contract, the clinical Phase II study was designed to determine the safety and the optimal combination/dose of an injectable H5N1 influenza vaccine (30 and 45µg antigen) and Intercell's VEP (50 and 100µg LT adjuvant) applied at the injection site. A total of 500 healthy adults were recruited in 6 study groups.

The study did not identify the optimal combination of antigen and adjuvant because no statistically significant difference in seroprotection rates as measured by Haemagglutinin Inhibition (HI) assay was observed when comparing groups with and without VEP.

However, the study results demonstrated a good safety profile for all doses of injectable vaccine and adjuvant patches studied. Furthermore, a dose-dependent response to the H5N1 antigen was observed. Anti-LT IgG titers in study subjects receiving the patch confirmed that Intercell's VEP could consistently deliver the vaccine adjuvant.

Intercell intends to conduct further clinical evaluation using its VEP in combination with an injectable H5N1 vaccine to be supplied by GlaxoSmithKline (GSK) as part of a collaborative agreement signed in December 2009.

HHS and Intercell are currently considering the next steps for this development program.

"Single-dose protection against highly pathogenic pandemic influenza strains such as H5N1 is an important goal for pandemic protection, but one which has been shown to be challenging", said Thomas Lingelbach, Chief Operating Officer of Intercell and CEO & President Intercell USA Inc. "We think that despite the inconclusive results, our Vaccine Enhancement Patch is uniquely positioned to have the potential to achieve single-dose protection and hence Intercell using its partner GSK's vaccine intend to proceed with further clinical evaluation."

### **About Pandemic Influenza**

Three influenza pandemics occurred in the 20th century leading to the death of more than 50 million people globally, and the current H1N1 pandemic influenza is a reminder of the ongoing reality of such threats to public health. By U.S. government estimates, pandemic influenza has a greater potential to cause deaths and illnesses than virtually any other natural





health threat. Signs of a pandemic influenza have emerged in Southeast Asia, as lethal infections of poultry and humans with H5N1 avian influenza virus continue. This H5N1 virus is now endemic in bird populations, having spread to more than 40 countries and causing the deaths of hundreds of millions of birds. Furthermore, the World Health Organization reports that the number of avian influenza cases in humans has reached more than 370 cases in 14 countries.

### **About the HHS Pandemic Influenza activities**

Under the HHS Pandemic Influenza Plan of November 2005, key goals for vaccine preparedness are to stockpile enough pre-Pandemic Influenza vaccines to cover 20 million people in the critical workforce and to develop sufficient domestic manufacturing capacity to produce pandemic vaccine for the entire U.S. population of 300 million within 6 months of pandemic onset.

### **About Intercell's Vaccine Enhancement Patch**

Intercell believes that its Vaccine Enhancement Patch has the potential for the development of improved influenza vaccines, especially in the field of pandemic influenza. Pre-clinical studies and clinical trial results using the Vaccine Enhancement Patch with H5N1 vaccine suggest that this strategy may be used for other applications 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 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 Pfizer (formerly Wyeth).

The Company's pipeline of investigational products includes a Travelers' Diarrhea Vaccine Patch (Phase III), a Pseudomonas vaccine candidate (Phase II), a vaccine to prevent Pandemic Influenza combining our Vaccine Enhancement Patch 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, 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)



## Contact Intercell AG

### Intercell AG

Lucia Malfent

Vice President, Global Head Corporate Communications

Campus Vienna Biocenter 3, A-1030 Vienna

P: +43-1-20620-1303

Mail to: [LMalfent@intercell.com](mailto:LMalfent@intercell.com)

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