



## **Intercell starts European Pivotal Phase III clinical trial for the patch-based Travelers' Diarrhea Vaccine**

- » Placebo controlled field study to confirm vaccine efficacy in travelers to Guatemala and Mexico

**Vienna (Austria) and Gaithersburg (USA), October 14, 2009** – Intercell AG (VSE: ICLL) announced today that its Travelers' Diarrhea (TD) Vaccine Patch has entered clinical Phase III development. A pivotal efficacy field study started with the first subjects vaccinated in the United Kingdom. The randomized and placebo-controlled study with travelers from Europe to Mexico and Guatemala will evaluate the efficacy of the TD Vaccine Patch to actively immunize against moderate to severe ETEC (enterotoxigenic *E. coli*) disease in a field setting. The trial will be conducted in the European Union, mainly the UK and Germany, and will include 1,800 subjects travelling to Mexico and Guatemala.

“The start of our pivotal efficacy Phase III trial is a key achievement in the clinical development of the worldwide first vaccine delivered with a patch,” stated Thomas Lingelbach, COO of Intercell AG and CEO of Intercell USA. “ETEC is the main cause for diarrhea in travelers. Therefore, a patch-based TD vaccine has the potential to significantly reduce the disease burden, severity and incidence of travelers’ diarrhea episodes.”

The TD vaccine system consists of a self-adhesive patch containing the vaccine antigen, the LT – heat-labile toxin – from *E. coli*, and a single-use device used to prepare the skin at the site of patch administration, the Skin Preparation System (SPS). Intercell combines the classical toxin approach to vaccination with its innovative patch-based, needle-free delivery system. The SPS partially disrupts the stratum corneum of the skin. The dry patch contains the antigen in a stabilizing excipient formulation and delivers the antigen to the skin. Activated Langerhans cells take up the antigen and deliver it to the draining lymph nodes.

Diarrhea caused by enterotoxigenic *E. coli* (ETEC) is a disease associated with significant morbidity in travelers to areas of the world where fecal contamination of food and water is common. Travelers' diarrhea is generally a 4-5 day illness with frequent loose stools, usually associated with nausea, vomiting, abdominal cramps, prostration, and dehydration. ETEC is also implicated in new onsets of post-infectious irritable bowel syndrome (IBS), which affects 10 to 20% of travelers who develop Travelers' Diarrhea.

In an earlier randomized, double blind placebo-controlled Phase II field trial the vaccine showed excellent immunogenicity and reduced the risk of clinically significant diarrheal episodes in travelers to Mexico and Guatemala. The started Phase III trial with 1,800 subjects will evaluate the efficacy of the TD Vaccine for prevention of moderate to severe ETEC disease in the same field setting.



## About Travelers' Diarrhea

Travelers' Diarrhea (TD) is caused by consumption of contaminated food or water. The onset of TD normally occurs within the first week of travel, but may occur at any time, or even after returning home. An infection results in watery stools three or more times in a 24-hour period, sometimes in combination with fever, nausea, bloating, and abdominal cramps. Also, between 10 and 30% of those who develop TD will suffer from Irritable Bowel Syndrome (IBS), a chronic disorder of the intestine.

Annually, approximately 20 million out of nearly 55 million international travelers develop Travelers' Diarrhea while visiting endemic areas in Asia, Africa, and South America. Furthermore, Diarrhea caused by ETEC sickens 210 million children in endemic areas each year, killing more than 350.000 annually. Young adults and individuals with suppressed immune systems are at an especially high risk of infection.

Currently, there is no licensed vaccine targeting primarily TD and the most effective treatment of Diarrhea is oral rehydration therapy (ORT), the simple replacement of fluids and salts.

## 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 platforms include an antigen-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 Novartis, Merck & Co., Inc., Wyeth, and Sanofi Pasteur.

The Company's pipeline includes a Travelers' Diarrhea Vaccine Patch (Phase III), a Pseudomonas vaccine candidate (Phase II), a Vaccine Enhancement Patch to prevent Pandemic Influenza in combination 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, three other 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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