Intercell provides update on clinical trials for the patch-based Travelers' Diarrhea vaccine

- Travelers' Diarrhea vaccine candidate failed to meet efficacy endpoints to protect against enterotoxigenic E. coli (ETEC) (defined as cases in which ETEC LT, LT/ST or ST toxins are detected in diarrheal stool samples) mediated diarrheal infections in pivotal, randomized and placebo-controlled efficacy studies (Phase II and Phase III)
- However, the studies support the continued investigation of the patch technology as a suitable route of immunization for future potential vaccine candidates. The pivotal studies confirm that the vaccine candidate induces reproducible levels of protective antibodies against the LT toxin resulting in a meaningful reduction of LT specific ETEC episodes, following transcutaneous immunization.
- The projected year end loss for 2010 will be substantially higher than the previously expected EUR 40m since milestone payments in connection with the Travelers' Diarrhea program are not expected to be received, and the Company expects to impair all or a substantial part of its respective intangible assets.
- Intercell has taken the decision not to pursue further clinical development of its Travelers' Diarrhea vaccine candidate
- Intercell will reduce R&D expenses by approximately 40% in 2011 compared to 2010 and will realign its organizational structures accordingly
- Management is focusing the Company's R&D strategy and resources on the other projects in its well-balanced clinical stage portfolio, especially the successful and highly attractive nosocomial programs including the investigational vaccines against Pseudomonas and C. difficile as well as S. aureus developed with Merck & Co., Inc., and Management will continue to progress the positive trend of increasing sales of Intercell's Japanese Encephalitis vaccine

Vienna (Austria) and Gaithersburg (USA), December 12, 2010 – Intercell AG (VSE: ICLL) announced today preliminary clinical results on its investigational Travelers' Diarrhea (TD) Vaccine Patch program and the decision not to pursue further the development of this vaccine candidate. The decision was made following the receipt of results of its randomized and placebo-controlled Phase III study (ELT301) with 2036 travelers from Europe to Mexico and Guatemala as well as the pilot efficacy Phase II trial (ELT209) with 723 travelers from Europe to India.

Both trials were successfully conducted according to study design, met statistical targets of enrollment, participation follow-up, subject and site compliance, and produced a firm preliminary conclusion. The vaccine was generally well tolerated and the safety profile was consistent with that observed in earlier studies.

In an earlier randomized double blind placebo-controlled Phase II field trial (ELT206) the TD vaccine candidate showed excellent immunogenicity and reduced the risk of clinically significant diarrheal episodes in U.S. travelers to Mexico and Guatemala. The Phase III trial was intended to confirm the efficacy of the investigational TD Vaccine Patch for prevention of moderate to severe diarrhea in a similar field setting.

The trials' primary endpoints, reduction of incidence of all types of enterotoxigenic E. coli (ETEC) (defined as cases in which ETEC LT, LT/ST or ST toxins are detected in diarrheal stool samples) and/or all cause diarrhea (secondary endpoints) comparing the vaccine groups with the placebo group, were not met. Thus, in the ELT301 study a non-significant vaccine efficacy for about 35% for all type ETEC and no apparent effect on the frequency of all-cause moderate to severe diarrhea was observed. However, a statistically significant reduction of duration of all-cause diarrheal episodes and total number of unformed stools was observed, confirming observations from a previous Phase II study.

In study ELT301, the vaccine protected most against LT positive ETEC (up to 60%). However, the study was not powered to demonstrate a statistically significant efficacy against individual ETEC types. Furthermore the incidence of LT positive ETEC in both trials was lower than expected, compared to previous trials and published data.

The current trials have confirmed the previous Phase II observation of a consistent induction of protective levels of antibodies against the LT-toxin following transcutaneous immunization and using the Company's proprietary delivery technology. This clearly supports and validates patch-based vaccination as a suitable route of immunization for future potential product candidates.

Intercell is carrying out further analysis of the trial results. However, subject to this analysis and further consultation with its partner, the Company remains committed to expanding the development of the use of patch technology for existing or novel vaccines as well as the development of the investigational Vaccine Enhancement Patch (VEP) system for vaccination against Avian H5N1 Influenza.

Following the successful progression of the S. aureus vaccine candidate with recent positive Phase II data reported by Intercell's partner Merck & Co., Inc., the encouraging Phase II data in the Pseudomonas vaccine program and the imminent clinical entry of the Company's novel investigational C. difficile vaccine, R&D resources will be even more focused on the development of the nosocomial franchise. Hospital-acquired infections represent a major health need and Intercell is well positioned with its portfolio to help address this medical need.

Intangible assets pertaining to the TD vaccine program and other patch programs represented a book value of EUR 167m at September 30, 2010. Intercell expects to impair all or a substantial part of these assets following an impairment analysis triggered by the study results. Such impairment will have a substantial effect on the loss for the full year 2010. In addition, Intercell does not expect to receive the previously expected milestone payments in connection with the TD program in 2010 or going forward. Intercell has decided to substantially reduce Research and Development expenses by approximately 40% in 2011 compared to 2010 and will realign

its organizational structures accordingly. The measures are expected to be fully effective by mid 2011 and lead to further cost savings in 2012 and forward.

"We are extremely disappointed with these unexpected Phase II and III outcomes for our TD Vaccine Patch; however, we believe that we have a clear strategy to further develop our strong product portfolio in a balanced way. Our Japanese Encephalitis vaccine is on the market, and we have a world leading and highly attractive nosocomial vaccine franchise in advanced development and a series of promising vaccine and antibody pre-clinical candidates", states Gerd Zettlmeissl, Chief Executive Officer of Intercell. "We have taken all necessary managerial measures to fully realign the company's operations."

Given this unexpected situation, Intercell has decided to postpone its R&D Day planned for Wednesday, December 15 in London and will replace it by an Analysts' call to outline the data obtained and its strategic implications in more detail.

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 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, Romark, and Pfizer (formerly Wyeth).

The Company's pipeline of investigational products includes a Travelers' Diarrhea Vaccine Patch (Phase III), a Pseudomonas aeruginosa 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),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 is expected to enter Phase I clinical trials still 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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