



## **Intercell's Hepatitis C vaccine meets success criteria for further development – route and frequency of administration optimized**

**Vienna (Austria), January 31, 2006** – Intercell (VSE; "ICLL") today announced initial data from a clinical trial aiming at the optimization of its therapeutic Hepatitis C vaccine IC41. Results indicate that IC41, given in optimized route and schedule, is considerably more immunogenic than it has been shown previously.

These results will make it possible for Intercell to expand its leading position in Hepatitis C therapeutic vaccination through a clearly structured development plan that will include additional trials in Hepatitis C patients.

In the current trial, 50 healthy adults were vaccinated with IC41 in alternative regimes. In order to increase T-cell response, which plays an essential role in the natural defense against the Hepatitis C virus, various intervals, numbers and routes of vaccination were tested. In an IC41 Phase II trial that has already been completed, the strongest T-cell responses were associated with a clinically meaningful decline of HCV-RNA.

The optimization study shows that the T-cell responses were stronger and significantly more frequent than seen up to now. This was true for both CD4- and CD8- positive T-cells. Compared to the previous regime, the improvements were positive and meet the success criteria for further development. The favourable safety profile and local tolerability seen in previous trials involving approximately 300 healthy volunteers and Hepatitis C-patients was maintained. The final results of the study will be presented at the European Association for the Study of the Liver (EASL) congress April 26-30, 2006, in Vienna.

Based on these results, Intercell is now planning to test IC41 with this optimized schedule in a further Phase II trial in patients with chronic Hepatitis C. This study aims to show sustained reductions of HCV-RNA through IC41 stand-alone therapy in a substantial subset of patients. Intercell plans to start the trial in mid-2006, with first results expected in mid-2007. The estimated date for market launch is currently 2011.

Furthermore, results from an ongoing Phase II study in combination with Interferon/Ribavirin standard therapy are expected for mid-2006. The primary objectives of this study are safety and the pharmacodynamic interactions of IC41 with standard therapy. Intercell hopes the study will further support the development of IC41 in a combination therapy setting using the new and improved administration scheme of IC41.

"The significant improvement in critical T-cell responses in connection with the new optimized schedule and the viral load reductions that were observed in previous clinical trials with chronic Hepatitis C patients give encouraging support towards a further clinical Phase II trial to demonstrate the therapeutic effect of IC41", states Prof. Michael P. Manns from Hanover Medical School, key investigator in Intercell's past and upcoming patient trials.

“We are following a very straightforward development strategy. The results of the optimization trial are encouraging and confirm our scientific and clinical approach in the development of a therapeutic Hepatitis C vaccine to meet a substantial medical need”, states Gerd Zettlmeissl, CEO of Intercell.

### **About Hepatitis C**

HCV is a major cause of chronic liver disease, including cirrhosis and liver cancer. According to the World Health Organization (WHO), worldwide, approximately 170 million people are chronic HCV carriers (3% of the world’s population), including about 10 Million Europeans, 3.9 Million Americans and 2 Million Japanese. 35.000 new infections occur in the United States alone each year. The substantial unmet medical need is underscored by the fact that each year 8.000 to 10.000 deaths and 1.000 liver transplantations in the United States are due to HCV.

Currently, there is no vaccine or immunotherapy against Hepatitis C and the infection can only be treated with a combination of Interferon and Ribavirin – a long-term therapy with limited efficacy and substantial side effects. It also gives rise to high treatment costs for patients. In 2002, worldwide sales of HCV drugs totaled at around EUR2.8bn, and demand has since grown significantly. The market is seen to be expanding to EUR3.5bn by 2006.

### **About Intercell AG:**

Intercell AG is a growing biotechnology company which focuses on the design and development of novel vaccines for prevention and treatment of diseases for which there exists substantial unmet medical need. The Company develops antigens and immunizers (adjuvants) which are derived from its proprietary technology platforms and has in-house GMP manufacturing capability. Intercell has strategic partnerships with a number of global pharmaceutical companies, including sanofi pasteur, Merck&Co., Inc., SciGen Ltd. and the Statens Serum Institut. The Company has a broad development pipeline with a vaccine for Japanese Encephalitis in Phase III, a vaccine for Hepatitis C in Phase II, partnered vaccines for Tuberculosis and *S. aureus* which are in Phase I and five products focused on infectious diseases in pre-clinical 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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