



## Intercell's therapeutic Hepatitis C vaccine meets primary endpoints in Phase II

- » **Data from 50 patients reveal statistically significant viral load reduction and favorable safety profile**
- » **Data confirm findings from Interim Analysis from Q3 2007**
- » **Further clinical trials in Co-development with Novartis will include IC31®**

**Vienna, Austria, February 6, 2008.** Today, Intercell AG (ICLL) announced the analysis of Phase II data for its peptide-based therapeutic Hepatitis C vaccine (IC41) in an exploratory clinical study targeting treatment-naïve Hepatitis C patients. The vaccine comprises five synthetic T-cell peptides and Intercell's first-generation poly-arginine adjuvant (IC30). It is designed to stimulate T-cell responses against viral protein structures conserved throughout the major HCV genotypes, in order to reduce viral load in the blood of chronically infected patients.

The current study comprises 50 patients chronically infected with Genotype 1 of the Hepatitis C virus, which is known to be very difficult to treat with Interferon/Ribavirin standard therapy. The patients enrolled in the study have not received any other therapy and were given 8 intradermal injections of the IC41 vaccine in bi-weekly intervals for 14 weeks. This intensified vaccination schedule was derived from a recent optimization study aimed at improving the vaccine's T-cell immune response. The desired outcome of the ongoing study is the demonstration of a constant and sustained decline in HCV viral load that is increased by reiterative vaccinations during the treatment period.

"The new additional data obtained from our phase II study have confirmed and consolidated the encouraging trend seen in our previous interim analysis and thus, will provide a strong base to further strengthen our HCV franchise and to accelerate our efforts towards obtaining an HCV therapeutic vaccine, which could be a most valuable component in a combination treatment for HCV", states Alexander von Gabain, Chief Scientific Officer of Intercell.

In the current analysis, 50 patients have been enrolled. The data obtained show that the primary endpoint set for this study, namely a statistically significant sustained HCV-RNA decline, has been met.

In the second week after the final vaccination, a 40 % reduction of viral load was observed in comparison to the baseline prior to vaccination. The therapeutic effect of the vaccine on the viral load is small, but found to be significant when data were submitted for rigorous statistical analysis ( $p=0.0010$ ).

The results are especially significant in the light of the observation that viral load reduction is increasing with the number of vaccinations. The study included patients with various levels of viral load. In the subset of patients (N=25 with high viral load (> 2 million copies/ml) before



treatment, a more pronounced average decline of 60 % (0.4 log) was achieved with statistical significance ( $p=0.0001$ ).

Although options for the treatment of chronic Hepatitis C with Interferon/Ribavirin have improved, treatment will remain very difficult and a significant unmet medical need, especially in the case of Genotype 1. Immunotherapies, and possibly therapeutic vaccines, might become an option in the arena of existing and future HCV combination treatments. Thus, Intercell and its co-development partner for therapeutic Hepatitis C vaccines, Novartis, will define a further development strategy that will also take advantage of an enlarged antigen portfolio and of IC31<sup>®</sup>, Intercell's second-generation adjuvant that has recently demonstrated the generation of T-cell responses, in human vaccine trials, to a level not yet seen for other known adjuvants.

### **About Hepatitis C**

HCV is a major cause of chronic liver disease, including cirrhosis and liver cancer. According to the World Health Organization (WHO), approximately 170 million people worldwide 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 transplants in the United States are due to HCV.

Currently, there is no vaccine 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 totalled around EUR 2.8bn, and demand has since grown significantly. The market has been seen to expand to about EUR 3.5bn by 2006.

### **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/II)



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".

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