

### **Intercell's therapeutic Hepatitis C vaccine safe in combination with standard therapy**

- » Phase II combination trial for therapeutic Hepatitis C vaccine (IC41) completed. Started in 2003 the study was still conducted with a not optimized vaccination schedule.
- » Good safety profile of IC41, when used concomitantly with standard therapy (Interferon and Ribavirin) - standard therapy did not show any interference with the immune response of IC41. In the responders to the combination treatment (14 patients), vaccine specific T-cell levels substantially increased as compared to the non-responders (8 patients)
- » Proof-of-concept Phase II efficacy study with the new previously optimized immunization schedule in patients is ongoing - initial results expected in mid 2007.
- » The study is the first step towards potential combination therapy settings where the meanwhile improved administration scheme of IC41 is available.

**Vienna (Austria), December 12, 2006** – Intercell AG (VSE, "ICLL") announced today that it has completed a Phase II trial for its therapeutic Hepatitis C vaccine (IC41), where the vaccine was applied in combination with the standard Hepatitis C therapy (pegylated Interferon and Ribavirin – PegIFN-RBV) to patients infected with genotype 1. In the study, the vaccine administration was bound to the schedule of the first patient trial concluded in 2004 where route and frequency was still sub-optimal as compared to the improved induction of pivotal T-cells achieved in recently concluded optimization trial.

In the current clinical trial, chronically infected Hepatitis C patients receiving standard therapy with PegIFN-RBV were enrolled in Germany, Austria and in the UK. 22 patients who had an early response at week 12 to standard therapy received vaccinations with IC41 as an add-on to standard therapy during the second half of their treatment (week 28 to 48).

The study proved a good safety profile of IC41 when used concomitantly with PegIFN-RBV. Furthermore, the level of the critical T-cell response generated was similar to what had been seen in previous studies in which chronic patients or healthy subjects were vaccinated with IC41 alone, indicating that there was no apparent interference of PegIFN-RBV with vaccine immunogenicity. Moreover, it was observed that critical anti-HCV T-cell responses could only be measured in the group of non-relapsing patients (14 out of 22), whereas such responses were absent in the 8 relapsing patients. As expected, however, an improved relapse rate by the concomitant use of IC41 could not be demonstrated with statistical significance, given the use of the non-optimized vaccination schedule.

"Considering the well-known limitations of currently approved Hepatitis C therapies we are well on track with the development of our therapeutic vaccine. It was key to demonstrate that IC41 can be safely administered together with standard therapy, thus enabling the way to potential future combination therapies", states Alexander von Gabain, Intercell's Chief Scientific Officer.



Intercell has recently initiated a Phase II proof-of-concept – efficacy study in chronic Hepatitis C patients. Here, an optimized immunization schedule will be applied to patients infected with genotype 1, who are naïve to treatment. The study aims to show a significant decline in HCV viral load, which would be a clinical proof of the mechanism of IC41, and an important milestone to further advance the development. This is particularly true in genotype 1 patients, where standard therapy achieves a sustained viral response only in less than half of treated patients.

### **IC41 – Clinical development strategy**

After completion of a first Phase II clinical study in patients not responding to standard therapy in 2004, the clinical development program has been extended. A follow-up study has been designed to further increase the T-cell response, which is the most critical part of the immune system in the fight against the infection, by optimizing the route and the frequency of vaccinations.

Results of the optimization clinical trial, which was completed in Q1 2006, indicate that IC41, when given in optimized route and schedule, is considerably more immunogenic than has previously been shown.

Based on these results, Intercell has started a Phase II Proof-of-concept study testing IC41 with this optimized schedule in a further Phase II clinical 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. Initial results of this study are expected in mid 2007.

### **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 transplantations 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 totaled at around EUR 2.8bn, and demand has since grown significantly. The market is seen to be expanding to EUR 3.5bn by 2006.

### **About Intercell AG:**

Intercell AG is a biotechnology company focused on the research, development, manufacturing and future commercialization of innovative vaccines for the prevention and



treatment of infectious diseases, for which there exists a substantial unaddressed medical need. Intercell 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 Novartis, Wyeth, Sanofi Pasteur S.A., Merck & Co., Inc., Kirin Brewery Co., Ltd. and the Statens Serum Institut. Intercell has a broad development pipeline with a vaccine product candidate for Japanese Encephalitis in Phase III clinical trials, a vaccine product candidate for Hepatitis C in Phase II, partnered vaccine candidates for Tuberculosis and S. aureus, which are in Phase I, and more than five other product candidates 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)

**Contact Intercell AG:**

**Intercell AG**

Katharina Wieser

Head of Corporate Communications

Campus Vienna Biocenter 2, A-1030 Vienna

P: +43-1-20620-303 Mail to: [kwieser@intercell.com](mailto:kwieser@intercell.com)

*This communication expressly or implicitly contains certain forward-looking statements concerning Intercell AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of Intercell AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Intercell AG is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.*