

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

- » *First data from 25 patients reveals statistically significant viral load reduction and very good safety profile*
- » *Data opens door for therapeutic vaccination in the arena of existing and future treatment options – but not yet a breakthrough for vaccination as monotherapy*
- » *Data still has to be interpreted with caution given the small sample size – full study data expected for Q1 2008*

Vienna, Austria, 20 August 2007. Today, Intercell AG (ICLL) announced the analysis of Phase II interim data for its peptide-based therapeutic Hepatitis C vaccine (IC41) in an exploratory clinical study targeting treatment-naïve Hepatitis C patients. The vaccine comprises eight T-cell antigens 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.

In the current interim analysis, 25 patients have been evaluated in the "per protocol" population. The data obtained shows 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 (0.2 log) 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 was submitted for rigorous statistical analysis ($p=0.0178$).

The results are especially significant in the light of the observation that viral load reduction is increasing with the number of vaccinations and is most pronounced two weeks after the vaccination schedule has been concluded. The study included patients with various levels of viral loads. In the subset of patients ($N=12$) with high viral load (> 2 million copies/ml) before treatment, a statistically significant ($p=0.0168$) average decline of 60 % (0.4 log) was achieved. Thus, it seems that the therapeutic effect is more pronounced when the patients' immune system is unable to keep the viral load in check.



Final results of the study with the full set of patients and an analysis of HCV-RNA and T-cell responses until 24 weeks after the last vaccination are expected in early 2008. Furthermore, an extended analysis of how the therapeutic effect relates to the induction of T-cell responses has to be awaited until the final outcome of the trial.

Although the interim analysis is restricted by the limited number of subjects evaluated at this stage, the present findings – if confirmed by the final data – would indicate for the first time that a therapeutic vaccination schedule is able to reduce HCV viral load and has thereby potentially opened a new door for HCV treatment.

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 might also take advantage of an enlarged antigen portfolio and of IC31[®], 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.

“The new data obtained encourages us very much to further strengthen our HCV franchise and to accelerate our efforts towards obtaining an HCV therapeutic vaccine”, 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), 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 Intercell's 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., 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 regulatory process towards a Biologics License Application (BLA) to the US Food and Drug Administration (FDA) has been initiated. The broad development pipeline includes a Pseudomonas vaccine in Phase II, a therapeutic vaccine for Hepatitis C in II, partnered vaccines for Tuberculosis and S.aureus, which are in Phase I, 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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