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Thursday 6 September 2007



New flu vaccine from PepTcell could provide immunity against all strains of influenza virus

Data published in leading academic journal

High Wycombe, UK - 6th September 2007 Data showing how a new flu vaccine from PepTcell has the potential to protect against all strains of influenza, including pandemic and annual, has been published in this month's *European Journal of Immunology*.

The pre-clinical results show how mice vaccinated with PepTcell's novel flu vaccine, Flu-v, had a significantly increased survival rate when challenged with a lethal dose of influenza virus, compared with those that received a control vaccine.

Dr Wilson Caparros-Wanderley, PepTcell's Chief Scientific Officer said: "These are extremely encouraging results for PepTcell's Flu-v vaccine. They show that a vaccine, targeted at parts of the virus which do not change from year-to-year, can be effective against lethal influenza strains."

The data showed how PepTcell has used a novel proprietary prediction algorithm to locate conserved immunogenic regions in animal and human strains of flu virus. The analysis identified six highly conserved regions within several proteins that are capable of triggering an immune response.

These six regions were then chemically synthesised as small protein fragments called peptides. The resulting preparation, Flu-v, was used to immunise eight transgenic mice. At the same time a group of eight control mice were immunised with a set of non-related peptides.

Following immunisation with Flu-v the mice launched a specific T-cell immune response of the CD8⁺ subtype against the peptides. T-cells are part of the immune system, helping to fight off infection and disease by killing abnormal cells. The CD8⁺ T-cells isolated from the mice showed activity against human cells infected with three unrelated influenza strains in *in vitro* tests. This experiment confirmed that the peptide sequences in Flu-v are highly conserved across strains, and that these peptides are naturally presented on the surface of flu-infected cells, and therefore can be recognised by the immune system.

When the immunised mice were subsequently challenged with a lethal dose of influenza, the researchers found that fifty seven percent of the mice who had been immunised with the Flu-v vaccine survived, compared with none of the mice in the control group.

Greg Stoloff, Managing Director of PepTcell, commented: "These results suggest that PepTcell's Flu-v vaccine could eliminate the need for annual flu vaccination as the immunity generated targets regions of the virus that remain constant. The results also suggest that Flu-v has the potential to provide effective protection against a pandemic flu strain by enabling stockpiling and the initiation of a worldwide vaccination program ahead of an outbreak."

PepTcell is in the process of finalising all the manufacturing processes for its vaccines, and expects Flu-v to enter Phase I clinical trials during 2008.

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NOTES FOR EDITORS

About the *European Journal of Immunology*

Gregory A Stoloff, Wilson Caparros-Wanderley: Synthetic multiepitope peptides identified *in silico* induce protective immunity against multiple influenza serotypes. Volume 37, Issue 9 (September 2007). *European Journal of Immunology*. 2007. Copyright Wiley-VCH Verlag GmbH & Co. KGaA. Reproduced with permission.

About PepTcell Ltd

PepTcell is a biotechnology company focused on applying its breakthrough technology to the development of a new class of vaccines – T-cell vaccines – against highly mutagenic viruses. The Company began operating in 2004, however the founding shareholders and key employees have been working on this novel concept for over 20 years.

Since its inception, the Company has completed the majority of its pre-clinical work for its influenza and HIV vaccines. PepTcell's lead product Flu-v, a single treatment flu vaccine is about to enter clinical trials in the UK. The vaccine, developed to be effective against all strains of flu virus (technical animation available) could eliminate the need for annual flu vaccinations.

PepTCell, a private Company, headquartered in High Wycombe, UK is in the process of finalising all the manufacturing processes for its Flu-v vaccine, and successfully raised capital from a range of investors.

For further information please visit the website at www.peptcell.com

PepTcell's Influenza Vaccine – Flu-v

The Company's lead product, Flu-v, has been developed to provide a single treatment flu vaccine which is effective against all strains of flu virus, including pandemic strains.

Current flu vaccines only work against specific virus strains. As these strains mutate frequently, vaccines also need to be updated. As such they do not provide protection against emerging flu strains, such as seasonal or avian flu. Using a novel proprietary epitope prediction algorithm, PepTcell has successfully identified immunogenic regions of flu virus that have not changed over 60 years, in both human and animal strains of the virus. This allows Flu-v to target conserved regions of the virus conferring long-term protection against the threat of emerging strains.

Unlike traditional vaccines which are grown in highly specialised facilities and whose production is limited by egg supply and the process of growing a vaccine, Flu-v can be quickly and easily manufactured in chemical plants. This allows the vaccine to be made and administered in large quantities prior to a pandemic outbreak, enabling a large proportion of the world to be protected. The vaccine has now reached a very exciting stage of its development. The majority of preclinical proof of principle studies are complete and the vaccine will soon begin clinical trials in the UK.

About Influenza

Influenza pandemics are caused when new strains of influenza viruses to which humans have no immunity develop the ability to replicate and spread efficiently in humans. Historically, pandemics have occurred three to four times per century, with twentieth-century pandemics occurring in 1918, 1957 and 1968. The most severe of these was the 1918 'Spanish influenza' pandemic, in which an estimated 40 million people died worldwide. All three of the twentieth century pandemics were caused by viruses related to avian influenza.⁶ In 2005, the World Health Organization (WHO) issued a statement noting that the world is 'closer to a further pandemic than it has been at any time since 1968'.⁷ This is largely because of outbreaks of disease caused by the so-called 'H5N1' strain, which has recently become widespread in bird populations in South- East Asia. Since December 2004, it is estimated that

over 250 human cases of H5N1 avian influenza have been treated globally, with a fatality rate (i.e. infected individuals killed by the virus) of 60%.

Find more information on Flu-v visit www.peptcell.com

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