



Universal influenza vaccine a step closer

London, UK, 9 November 2015 – Today, London-based PepTCell Limited, trading as SEEK, announces a collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH), to jointly lead a study⁽¹⁾ of SEEK's universal flu candidate, FLU-v.

The trial will assess the safety and immunogenicity of a cross-seasonal universal flu candidate. In a 'challenge' trial patients are first provided with the trial medication and then 'challenged' with a known pathogen.

NIAID and PepTCell Limited have entered into a Cooperative Research and Development Agreement (CRADA) to evaluate the efficacy and safety of SEEK's novel vaccine, FLU-v, a peptide-based vaccine that stimulates a cytotoxic T lymphocyte and non-neutralising antibody response against influenza. FLU-v may have potential as a cross-protective vaccine for multiple strains of influenza. Clinical studies will be performed to evaluate the efficacy and safety of SEEK's FLU-v vaccine in the setting of the NIAID influenza human challenge model.

The announcement of the NIAID collaboration and the US-based trial follows the low efficacy of last year's annual influenza vaccine. The vaccine was not as effective as required, preventing only 23 out of every 100 vaccinated people from developing flu symptoms.⁽²⁾ Existing antivirals (oseltamivir and zanamivir), intended to be used in infected patients, have also been shown to be of insufficient efficacy in reducing the burden of influenza.⁽³⁾



Flu – annual vs universal

Flu kills between 250,000 to 500,000 people globally every year.⁽⁴⁾ In 2014, the influenza virus mutated resulting in the annual influenza vaccine, given to many thousands of people, being relatively ineffective.⁽²⁾ The annual vaccine has to be recreated and approved each year as the new season's influenza virus strains emerge. These newly formulated vaccines can result in poor levels of protection when the vaccinated strains are mismatched (as they were during the 2014-15 season).

This will allow government agencies to stockpile the vaccine against the threat of annual and pandemic disease, as well as being able to administer treatment at the start of the annual flu season.

Gregory Stoloff, Chief Executive Officer of SEEK commented:

“Following successful Phase I and II human trials in the UK, the current on-going Phase IIb study in Europe and this newly announced challenge study in the U.S., in collaboration with the NIH, we will have a very strong data package to support our applications for licenses for FLU-v. Given the desperate need for effective products in this area, favourable results from these studies could enable breakthrough status or fast track approval process being granted to this product as well as funding support from Government backed programmes.”

If you would like to find out more, please visit:

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About the SEEK Group:

SEEK's strategy is to bring safe, effective and low cost medicines to patients as quickly as possible. It does this by using the most advanced understandings in biology and chemistry in the generation of the products through modifications to existing medicines to improve their efficacy, by using existing medicines in new indications or by creating new chemical entities ("Pioneering Science") and finds the fastest regulatory pathways to bring these products to patients ("Commercially Delivered").

SEEK Group includes investments in;

infirst HEALTHCARE

This is the consumer healthcare and primary care arm of the company, with a focus on bringing innovative new treatments for cough/cold, inflammatory pain and wound healing to market.

Health Clinics Limited

The Health Clinics offer services in the area of oncology, diabetes, transplantation and intracellular infectious diseases. The aim of the clinics is to offer safe, effective and low cost medicines for these diseases while providing the patients with a high quality of life during the course of their treatment.

References

1. Phase II Study of the Efficacy and Safety of FLU-v, PepTCell Limited's Proprietary Peptide-Based Universal Influenza Vaccine Containing Conserved T Cell Epitopes in the National Institute of Allergy and Infectious Diseases' Influenza Human Challenge Model.
2. Flannery, B et al Early Estimates of Seasonal Influenza Vaccine Effectiveness — United States, January 2015 Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control and Prevention (last accessed September 2015)
3. Cochrane Community. Tamiflu and Relenza: getting the full evidence picture <http://community.cochrane.org/features/tamiflu-and-relenza-getting-full-evidence-picture> (last accessed July 2015)
4. World Health Organisation (WHO), Media Centre, Fact sheets, Influenza – seasonal <http://www.who.int/mediacentre/factsheets/fs211/en/> (last accessed July 2015)