OTAGO INNOVATION
A UNIVERSITY OF OTAGO COMPANY

Developing a treatment for Herpes Simplex Virus Type 2 (HSV-2) in humans

Background

This project is based on the development of a treatment for HSV-2, which primarily causes genital herpes in humans. HSV-2 causes transient infection of epithelial cells in the genital mucosal epithelium. Following this infection the virus gains access to the sensory neurons where it is capable of producing a lifelong persistent infection. Periodic reactivation of HSV causes infection of the genital epithelia, resulting in asymptomatic virus shedding or ulcerative disease which can then be transmitted.

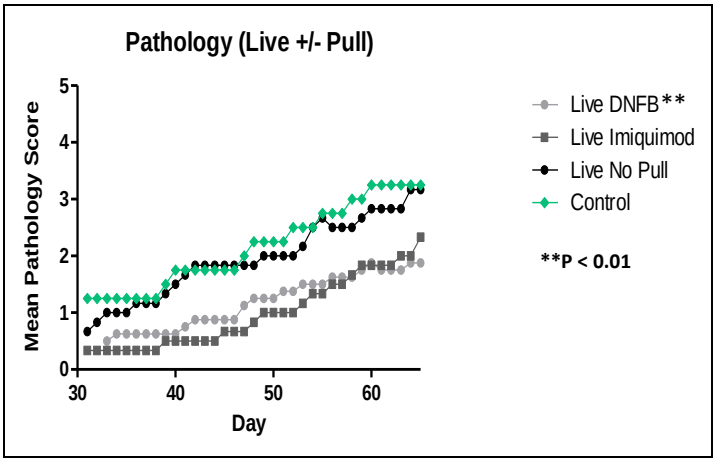
HSV-2 causes 70-80% of genital herpes cases. The symptoms of genital herpes are worst during the early stages of infection with the formation of painful fever blisters on or near the genitals. For the large part, HSV-2 infection presents no serious health risk, however in terms of sexually transmitted infection social stigma, HSV-2 ranks second only to HIV. HSV-2 also increases susceptibility to HIV acquisition.

Technology Overview

We have access to a novel formulation technology for improving the oral bioavailability of compounds via Immune Solutions Ltd (ISL). ISL is a wholly owned subsidiary company of University of Otago. Liporale™ is a lipid based, oral delivery platform proprietary to ISL.

We have deployed the Liporale™ technology which has proven the establishment of very strong immunity in mice to HSV-2. Our first experiment showed that oral immunisation with Liporale™ + HSV-2 antigen, coupled with induced mild vaginitis 'intravaginal pull', protects mice against HSV-2 spinal cord infection. A prophylactic effect was demonstrated in mice through prevention of HSV-2 infection in the dorsal root ganglia, and a reduction in vaginal pathology.

We have then undertaken a small Proof of Concept Herpes vaccine and challenge study in 48 guinea pigs. Our second experiment showed Liporale ™ + live attenuated HSV-2 antigen + DNFB (2,4-Dinitro-1-Fluorobenzene) significantly reduced viral reactivation and vaginal pathology (Fig. 1) but did not clear dorsal root ganglia infection (Fig. 2). Results indicate that the technology may well be therapeutic in effect.



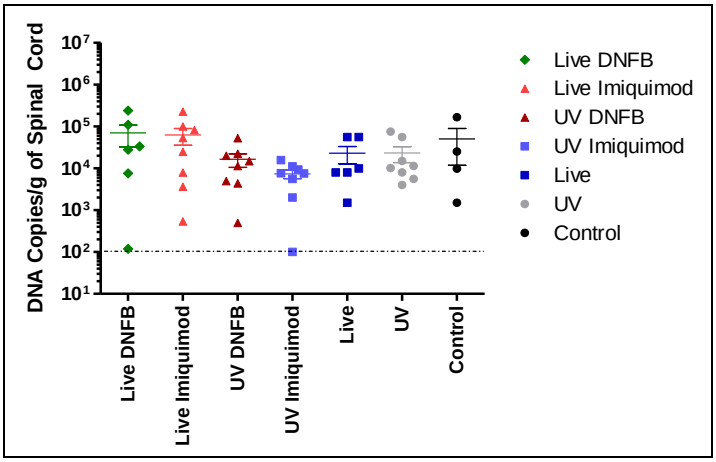


Figure 1: Pathology (days 30-65): live vaccine + pull

Figure 2: Viral load in dorsal route ganglion

Benefits

We aim to produce the first **oral** human therapeutic vaccine for HSV-2. Immunity against HSV-2 infection is dependent on local memory responses in the genital tract. We anticipate an oral vaccine that, when coupled with 'intravaginal pull' would induce mucosal immune responses in the genital tract, and as such demonstrate a therapeutic effect to protect against HSV.

Antivirals are amongst the most common treatment for herpes infections. There are some limitations associated with the use of antivirals, in that they can cause drug related toxicity as a result of their interference with the natural metabolism of the human body. Also, with the virus subsequently developing resistance against existing antivirals, the need for innovative therapies for the treatment of herpes simplex infection, and the search for novel antiviral drugs continues. This, therefore, presents a large potential for the growth of herpes simplex therapeutics market in future.

A therapeutic HSV-2 vaccine would be used to treat people already infected with the HSV-2 virus. A therapeutic vaccine could be of greatest interest in the developed world, to sufferers because of the significant social stigma associated with genital Herpes infection.

Opportunity

This technology is available for co-development activity. The University are seeking to engage with potential commercial partners to further develop this technology. This technology has been developed in collaboration with Queensland University of Technology.

IP Status

Provisional patent filed.

For further information contact:

Dr Tracey Smith, Commercialisation Manager
Immune Solutions Limited
tracey.smith@otagoinnovation.com
Phone. (0064) 3 4799970