

## SYNOPSIS

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|--------------------------|---|
| Name of Sponsor:         | Genetic Immunity Kft.<br>Fő utca 68.<br>Budapest 1027<br>Hungary<br><br>Phone: +36 1 201 9234<br>Fax: +36 1 201 2817<br>Email: <a href="mailto:zsolt.lisziewicz@geneticimmunity.hu">zsolt.lisziewicz@geneticimmunity.hu</a>   |
| Name of finished product | DermaVir Patch (LC002)  |
| Title                    | GIEU006: A Phase II Randomized, Placebo-Controlled, Multi-Center Study to Evaluate the Safety, Tolerability, Immunogenicity, and Antiretroviral Activity of DermaVir Patch (LC002) in Treatment-Naïve HIV-1-Infected Patients   |
| Short title              | DermaVir patch (LC002) in HIV-1 infected treatment-naïve patients   |
| Design                   | Randomized, placebo-controlled trial  |
| Sample size              | Total 36 patients   |
| Population               | HIV-1 infected adults<br>Antiretroviral treatment-naïve<br>CDC A, B category<br>Documented CD4 $\geq$ 400 cells/mm <sup>3</sup><br>HIV-1 RNA viral load 5,000 – 150,000 copies/mL   |
| Clinical Phase:          | Phase II  |
| Planned study period:    | From November 2007 to February 2009   |
| Dosing Unit              | LC002 vaccine standard unit per patch: 0.1 mg DNA = 0.8 mL of LC002 vaccine; patch size is 80 cm <sup>2</sup>   |
| Regimen                  | Patients will be randomized to one of the following 6 arms:<br>Arm 1: Low dose active patch (2 patches, n=9)<br>Arm 2: Low dose placebo patch (2 patches, n=3)<br>Arm 3: Medium dose active patch (4 patches, n=9)<br>Arm 4: Medium dose placebo patch (4 patches, n=3)<br>Arm 5: High dose active patch (8 patches, n=9)<br>Arm 6: High dose placebo patch (8 patches, n=3)<br><br>Schedule of immunization (study week): 0, 6, 12 & 18.<br>Study visits (study week): -4 (screening), 0 (baseline), 3, 6, 9, 12, 15, 18, 21, 24, 36, 48, 72 & 96. |
| Duration                 | 24 weeks with an additional 258 weeks (5 years) of follow-up for safety evaluation  |

Objectives

Primary objectives:

To evaluate the safety and tolerability of the DermaVir patch (LC002) in antiretroviral therapy naïve adults infected with HIV-1.  
To establish a safe and well tolerated dosing regimen of the DermaVir patch (LC002) in antiretroviral therapy naïve adults infected with HIV-1.

Secondary objectives:

To assess the antiretroviral activity of the DermaVir patch (LC002) by HIV-1 RNA measurements in antiretroviral therapy naïve adults infected with HIV-1.

To investigate changes in CD4+ and CD8+ T-cell counts during DermaVir patch (LC002) treatment in antiretroviral therapy naïve adults infected with HIV-1.

To assess the immunogenicity of DermaVir patch (LC002) in antiretroviral therapy naïve adults infected with HIV.

Main criteria for inclusion:

Asymptomatic HIV-1 infection  
Antiretroviral treatment-naïve  
CD4 count > 400 cells/mm<sup>3</sup>  
Viral load 5,000 – 150,000 copies/mL

Main criteria for exclusion:

HIV-2, HBV, or HCV co-infection  
Clinically relevant laboratory abnormalities  
Newly diagnosed HIV-related condition  
Active skin or auto-immune disease or sunburn  
Use of other HIV vaccines or immune modulating agents