# TCATF 189 02

**(Relates to SOP No. TCATS CTL 003)**

# Cytotoxic T-Cell Therapy for Epstein-Barr Virus-Associated Lymphoproliferative Disease: Patient Information and Consent

## Patient Information Sheet

This information is provided because you have been offered an unlicensed product, ie. one not licensed for commercial use, and which is selected specifically to match your tissue type. A healthcare professional will go through this information with you, explain what it all means and answer any questions you may have.

### What is Epstein-Barr virus-associated lymphoproliferative disease?

This disease can happen when the immune system is not working as it should. Epstein-Barr virus infects most people without causing much illness (except when it causes glandular fever). Once infected, you carry this virus all your life normally without any physical effect. The virus-infected cells are kept under control by special white blood cells known as cytotoxic T-lymphocytes, 'killer cells', in the immune system. If the immune system is not working properly, e.g. because of immunosuppressive drugs, age or genetic pre-disposition, the cells infected by the virus can grow out of control.

### How do we normally treat EBV lymphoproliferative disease?

In immunosuppressed patients, reduction of immunosuppression may help but carries a risk of transplant rejection. Cytotoxic drugs and monoclonal antibodies such as rituximab may be used but sometimes these therapies cannot be used or are not effective.

### What is this new treatment?

This involves an infusion of 'killer cells' specific to EBV, which have been expanded in culture from healthy blood donors. The donor cells are selected for you based on best available tissue match. These killer cells will be infused in hospital, under close supervision, at weekly intervals for 4 weeks. Test blood samples will be taken to identify best available CTL when you are being considered for the treatment, then another sample 12 weeks after the last CTL infusion to monitor effect of the treatment. Whether you stay in hospital for each treatment will be decided by your medical team.

### How effective has this treatment been in other patients like me?

In a previous study of patients with a similar condition, over half of patients responded to their cellular infusions. Of these, most have remained free of their disease.

### How do I know this is safe?

This cell therapy has been produced under strictly controlled conditions, in licensed premises following European regulations for Good Manufacturing Practice. All medical products carry a small amount of risk and you should always ensure you seek professional medical advice if you experience any problems.

### What side effects may this treatment have?

None of the original patients who received this treatment in a clinical trial experienced any serious problem, but side effects from the infusion of these cells may include fever, flushing, a rash and a drop in blood pressure. It is theoretically possible that the infusion may cause a condition known as Graft versus Host Disease, which may be fatal. Every precaution is taken to avoid these side effects.

### Confidentiality

This treatment has only been used with a limited number of patients. Although promising results have been obtained, the treatment is still at an early stage of development. It is therefore important that we gather information on your progress from blood samples and your medical records and this information may be published for scientific purposes to improve our knowledge and help others. We guarantee that your identity will be kept strictly confidential at all times.

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## Patient Consent Form

I …….. (print name) / date of birth …….. hereby consent to receive cytotoxic cell Therapy for Epstein-Barr virus-associated lymphoproliferative disease.

(Initials please)

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| I confirm that the purpose of the treatment and possible side effects of the treatments have been explained to me and that I have received and read patient information sheet TCATF 189 and that I understand its implications. | |
| I understand that this form of treatment is not commercially licensed and is specially issued to me as a named patient. | |
| I agree that blood samples I give are for checks before CTL treatment and my immunological status after treatment. | |
| I agree that details of my condition may be obtained from my doctors or medical notes, in order to monitor the success and side effects of this treatment. | |

Patient's / GUARDIAN signature _____ Date _____

Doctor's signature _____ Date _____