TCATF 189 04

(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 recommended treatment with an unlicensed product, i.e. one not licensed by the regulatory authority in the UK (the Medicines and Healthcare Products Regulatory Authority). It has been requested by your treating clinician as you have a special clinical need that cannot be met by licensed medicines, and has been 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 well as it should. Epstein-Barr Virus (EBV) infects most people without causing significant illness (it is the virus that causes glandular fever). Once infected, an individual carries this virus all their life usually without any ill effect. The virus-infected cells are kept under control by special white blood cells in the immune system known as cytotoxic T-lymphocytes ('killer cells'). If the immune system is not working properly, e.g. because of cancer or immunosuppressive drugs, the cells infected by the virus can grow out of control.

How is EBV associated lymphoproliferative disease usually treated?

In patients on immunosuppressive medication, reduction of the immunosuppression may help, but carries a risk of transplant rejection. Chemotherapy and monoclonal antibodies such as Rituximab may also be used but sometimes these therapies cannot be used or are not effective.

What is this treatment?

This treatment involves an infusion of 'killer cells' specific to EBV, which have been donated by healthy blood donors and expanded in the laboratory. The product selected for you is based on the best available tissue match between yourself and the donor of the cells. This cell product will be infused in hospital, under close supervision, at weekly intervals for 4 weeks. Test blood samples will be taken to identify the best available cell product when you are being considered for the treatment. A further sample is then repeated 12 weeks after the last infusion to monitor the effect of the treatment.

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

In a study of patients with a diagnosis of EBV-associated lymphoproliferative disease, over half of the patients responded to the cell infusions. Of these, most have remained free of this condition.

How do I know this is safe?

The cells required to manufacture this product have been donated by healthy blood donors who live either in the UK or New Zealand. All biological products carry some risk of disease transmission. In order to minimize this risk, as for all blood donations, the donors will have been carefully assessed and tested for a number of transmissible agents, including HIV and hepatitis. However, there is at present no test available for Variant Creutzfeldt-Jakob disease (vCJD) infection, nor any means of treating this condition, although donors who are identified at an increased risk of vCJD are excluded. The risk of transmitting infection or disease is considered to be low but can never be completely removed. The cell therapy product has been produced by the Scottish National Blood Transfusion Service under strictly controlled conditions, in licensed premises following UK 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 have any further questions or experience any problems.

What side effects may this treatment have?

None of the first patients who received this treatment in a clinical trial experienced any serious problem, but some side effects from the infusion of these cells may occur. The cell therapy product is stored frozen (cryopreserved) in a liquid containing dimethyl sulfoxide (DMSO), the DMSO being needed to allow the cells to remain active. Infusion of the fluid containing the DMSO commonly causes some mild transient side effects (occur in more than 10% of recipients), including a feeling of warmth

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spreading up the arm, into the chest and then into the head, abdomen and pelvis (your 'tummy'). A garlicky smell that lasts for several minutes is also common; others may be able to smell this on you for some hours afterwards. Other common side effects (occur in 1-10% of recipients) include nausea, low blood pressure, low heart rate, skipped beats, cough, headache, stinging on passing urine. Other possible side effects include fever, flushing and a rash. It is theoretically possible that the infusion may cause a condition known as Graft versus Host Disease, which may be fatal, but this is a rare side effect with this type of treatment. Every precaution is taken to minimise the risk of such side effects.

Confidentiality

This treatment has only been used in a limited number of patients. It is therefore important that we gather information on how patients (including yourself if you go ahead with the treatment) respond to the treatment by reviewing blood test results carried out and your medical records. Any information about you will be handled in strict confidence at all times. We may also use the information, in an anonymised manner, to publish the outcomes for scientific purposes to improve the general knowledge available on this condition – we guarantee that patients will not be identifiable from such publications.

Patient Consent Form

I …….. (print name) / date of birth …….. hereby consent to receive the Cell Therapy product for treatment of Epstein-Barr Virus-associated lymphoproliferative disease.

(Initials please)

I confirm that the purpose of the treatment and possible side effects have been explained to me, my questions answered satisfactorily and that I have received, read and understood the patient information sheet TCATF 189.	
I understand that this form of treatment is not commercially licensed and is specially issued for my treatment 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 medical team or medical notes, in order to monitor the success and side effects of this treatment and these details may be shared with the Scottish National Blood Transfusion Service (the manufacturer of the cell therapy product).	

Patient's / Guardian signature _____ Date _____

Doctor's signature _____ Date _____