Patient agreement to systemic anti-cancer therapy (SACT) **Tebentafusp**

Hospital/NHS Trust/NHS Board: **Responsible Consultant:**

Patient agreement to	Patient details		
systemic anti-cancer	Patient's surname/family name: Patient's first name(s):		
therapy (SACT)			
Tebentafusp			
•	Date of birth:		
	NHS number:		
	(or other identifier)		
Hospital/NHS Trust/NHS Board:	Special requirements:		
	(e.g. other language/other communication method)		
Responsible Consultant:			
Name:			
Job title:			
Name of proposed course of treatment (i	include brief explanation if medical term not clear)		
☐ Tebentafusp for the treatment of uveal meland	oma that is HLA2 positive		
Tebentafusp is given intravenously once every	y week (+/- 2 days).		
	a Ct		
Treatment is continued until loss of clinical beautiful continued until continued until loss of clinical beautiful continued until continued until continu	netit or unacceptable side effects.		
☐ Treatment is continued until loss of clinical beauthere will I have treatment? (tick all that a	·		

Statement of health profession

(to be filled in by health professional with appropriate k the hospital/Trust/NHS board's consent policy)

√ 1	Tick :	all	rele	var	nt I	has	(65
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Name:

Job title:

I confirm the	4' ()			
 I contirm the	nationt h	ae canacity	/ to an/	CONCONT

ſ		I have explained the	course of treatme	ent and intend	ded benefit t	to the	patient
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The intended benefits (there are no guarantees about outcome)

Disease control or palliative – the aim is not to cure, but to control or shrink the disease and improve both quality of life and survival.

Adjuvant – therapy given after surgery or radiotherapy to reduce the risk of the cancer coming back.

Neo-adjuvant – therapy given before surgery or radiotherapy to shrink the cancer, allow treatment and reduce the risk of the cancer coming back

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Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:	Other risks:			
Affecting more than 10 in every 100 (>10%) people	Heart issues like angina (chest discomfort or pain) is not common.			
 ☐ Cytokine Release Syndrome (CRS) is a common immune response. It is most common shortly after the first few doses. For this reason you will be asked to stay at the hospital after the first few treatments. It usually gets less severe and happens less often over time although it can still occur later. You will usually be given other medication before the first doses to reduce the risk of this happening. ☐ CRS is usually mild but can be severe which may potentially be life-threatening. It may lead to excessive inflammation, effects on different 				
	Tumor Lysis Syndrome is rare. This is when treatment destroys cancer cells too quickly for the kidneys to cope and leads to changes in blood tests.			
	Before treatment you may have blood tests to check for viruses (Hepatitis B or C, HIV, or unusual infections). Treatment may weaken your natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.			
organs and low blood cell counts. Very rarely you may need a short admission to an intensive care unit for extra support after treatment.	Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis,			
 Contact your treating team immediately if you have: a fever, tiredness, shortness of 	or both.			
breath, feeling or being sick, diarrhoea, fast heartbeat, headache.	Cancer and treatment for cancer can increase your risk of developing a blood clot			
Skin changes (rash, itch, redness, change in colour).	(thrombosis). A blood clot may cause pain, redness and swelling in a leg, or			
Feeling sick (nausea), being sick (vomiting), loss of appetite, tummy pain, diarrhoea, constipation, indigestion.	breathlessness and chest pain. Tell your doctor straight away if you have any of these symptoms.			
Tiredness and feeling weak (fatigue), chills, flu-like symptoms. Pins and needles in hands and feet, build-up of	Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal			
fluid in hands and feet.	dryness).			
 ☐ Headache, feeling dizzy, difficulty sleeping. ☐ Rapid heart rate, high blood pressure, flushing. ☐ Cough, shortness of breath. ☐ Changes in electrolyte levels such as low phosphate, magnesium, calcium, sodium and potassium levels – monitored with blood tests. 	Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant or make someone else pregnant during treatment and for 1 month afterwards. Use effective contraception throughout. Speak to your doctor			
☐ Anaemia (due to low red blood cells), changes in liver function – monitored with blood tests.	or nurse. Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every			
Occasional side effects:	in death. The risks are different for every individual. Potentially life-threatening			
Affecting between 1-10 in every 100 (1-10%) people	complications include those listed on this form,			
☐ Thinning of hair or hair loss, night sweats. ☐ Mild infection causing stuffy or runny nose, taste	but other exceedingly rare side effects may also be life-threatening.			
changes, mouth and throat pain.				
☐ Irregular heart beat.				
Muscle spasm.				
Feeling anxious.				
Changes in kidney fuction (monitored with blood tests).				

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Statement of health professional

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Pallent	identifie	r/label

Any other risks and information:	
☐ I have discussed the intended benefit and risks of available alternative treatments (including no treatments)	•
☐ I have discussed the side effects of the recomme straight away or in the future, and that there may be rare or have not yet been reported. Each patient may	some side effects not listed because they are
☐ I have discussed what the treatment is likely to in timing of the treatment, blood and any additional test	, , , , , , , , , , , , , , , , , , , ,
☐ I have explained to the patient, that they have the should contact the responsible consultant or team if	- -
☐ I have discussed concerns of particular important (please write details here):	
Clinical management guideline/Protocol con Yes No Not available If No please	npliant (please tick): e document reason here:
The following written information has been provided:	Health professional details: Signed:
☐ Information leaflet for Tebentafusp	Date:
24 hour alert card or SACT advice service contact details	Name (PRINT):
SACT treatment record (cruk.org/treatment-record)	Job title:
Other, please state:	
Statement of interpretor	
Statement of interpreter (where ap Interpreter booking reference (if applicable):	opropriate)
I have interpreted the information above to the patien believe they can understand.	t to the best of my ability and in a way in which I
Signed:	Date:
Name (PRINT):	Job title:

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your own copy of the form which describes the be	has been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you er questions, do ask – we are here to help you. You have ng after you have signed this form.	
☐ I have had enough time to consider my optio	ns and make a decision about treatment.	
☐ I agree to the course of treatment described	on this form.	
A witness should sign below if the patient is unab parental responsibility will be asked to sign for yo	ole to sign but has indicated their consent. A person with bung people under the age of 16 years.	
Patient's signature:		
Name (PRINT):	Date:	
Person with parental responsibility/witness' signa	ature:	
Name (PRINT):	Date:	
Confirmation of consent (health professional to complete when the patient attends for treatment, if the patient has signed the form in advance) On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead. Signed: Date: Name (PRINT): Job title:	Further information for patients Contact details (if patient wishes to discuss options later):	
	Contact your hospital team if you have any questions about cancer and its treatment.	
	Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for	
Important notes: (tick if applicable)	more information.	
☐ See also advance decision to refuse treatment☐ Patient has withdrawn consent (ask patient to sign and date here)	These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.	
Signed:	The project is supported by	
Date:	Cancer Research UK. This does not mean you are	

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taking part in a clinical trial.

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland, Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

- 1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- 2. Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- 3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

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