Patient agreement to systemic anti-cancer therapy (SACT)

Glofitamab with GemOx

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible Consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(e.g. other language/other communication method)

_____

_____

_____

_____

Name of proposed course of treatment (include brief explanation if medical term not clear)

☑ Glofitamab, Gemcitabine and Oxaliplatin for the treatment of Diffuse Large B-Cell Lymphoma (DLBCL) in adult patients.
☑ **Cycle 1 only :** Obinutuzumab intravenously on day 1. Gemcitabine and Oxaliplatin given intravenously on day 2 and Glofitamab given intravenously on days 8 and 15.
☑ **Cycles 2 – 8:** Gemcitabine, Oxaliplatin and Glofitamab are given intravenously on day 1.
☑ **Cycles 9 – 12:** Glofitamab (only) is given intravenously on day 1.
☑ Each treatment cycle lasts for 21 days. Treatment is continued for a maximum of 12 cycles, or less in the event of disease progression or unacceptable side effects.
☑ Growth factor (G-CSF) support by injection under the skin (subcutaneous) according to local protocol.
☑ In your first month of treatment, some of your injections may be given during inpatient stay.

Where will I have treatment?

☐ Outpatient ☐ Day unit/case ☐ Inpatient ☐ Other: _____

Statement of health professional

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

☑ Tick all relevant boxes

☑ I confirm the patient has capacity to give consent.

☑ I have explained the course of treatment and intended benefit to the patient.

The intended benefits (there are no guarantees about outcome)

☐ Remission induction (in some patients, long term responses can be achieved).

☐ Disease control (or palliative) – the aim is to control the disease, improve survival, prevent symptoms and improve quality of life.

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

- ☑ An inflammatory response called cytokine release syndrome (CRS) can affect different organ systems in your body with Glofitamab. It is usually mild but can be severe and life-threatening. You will have medicines before treatment to prevent this. It is important that symptoms are treated when they happen to stop them from getting worse. Tell your doctor or nurse immediately if you develop symptoms: fever, fast heartbeat, feeling dizzy or lightheaded, nausea, headache, rash, confusion, chills, breathlessness.
- ☑ An increased risk of getting an infection from a drop in white blood cells and reduction in antibody levels – it is harder to fight infections and you can become very ill.
- ☑ **If you have a severe infection this can be life-threatening. Contact your doctor or hospital straight away if:**
  - **your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team**
  - **you suddenly feel unwell (even with a normal temperature)**
- ☑ Feeling sick (nausea), being sick (vomiting). You will be given anti-sickness medication to prevent this (their side effects include diarrhoea, constipation, headaches).
- ☑ Tiredness and feeling weak (fatigue).
- ☑ Constipation, diarrhoea, tummy cramps.
- ☑ Sore mouth/throat and ulcers.
- ☑ Appetite loss, taste changes, weight changes.
- ☑ Hair thinning or loss.
- ☑ Skin reactions (rash, itching, dryness, colour changes).
- ☑ Headache.
- ☑ Bruising or bleeding (due to low platelets), anaemia (low red blood cells) causing tiredness, fatigue, shortness of breath.
- ☑ Oxaliplatin can cause numbness or tingling in hands and feet as well as in the throat (particularly in the cold) while being given or for several hours or days after stopping treatment. This is usually mild. In rare cases, this can be longer lasting. To help you, your nurse will slow your drip or temporarily stop it.
- ☑ Build-up of fluid causing swelling in the face, arms, hands, legs and feet (this usually resolves after stopping treatment).

Common side effects continued:

- ☑ Changes in electrolyte levels (monitored in blood tests).
- ☑ Shortness of breath (usually mild and passes without treatment), cough.
- ☑ This treatment can increase your blood sugar levels. If you have diabetes, monitor your blood sugar levels.
- ☑ Difficulty, pain or urgency when passing urine, blood or protein in the urine.
- ☑ In the first cycle of treatment with Glofitamab: tender swollen lymph nodes, chest pain, tumour flare (causing pain and swelling in the tumour area.
- ☑ Changes in kidney and/or liver function (monitored with blood tests).
- ☑ Reactions may happen while this treatment is being given or soon after. They are usually most noticeable with the first infusion: flu-like symptoms, back pain, high or low blood pressure, flushing, breathlessness, feeling or being sick, faster or irregular heartbeat, allergic reactions (severe reactions are less common).

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

- ☑ With Glofitamab: Effects on the brain (neurotoxicity or immune effector cell-associated neurotoxicity syndrome-ICANS) causing confusion, drowsiness, tremor. Other symptoms: difficulty speaking or understanding speech, agitation, dizziness, changes in handwriting. It is important to tell your doctor or nurse immediately if you have any symptoms.
- ☑ Do not drive, use tools or operate machines for at least 48 hours following the first two doses of Glofitamab.
- ☑ With Glofitamab: Hypogammaglobulinemia, where your body does not make enough antibodies which are important for fighting infections. If this happens, you may need treatment with antibody replacement therapy (intravenous immunoglobulins).
- ☑ Nail changes such as colour changes, fragile fingernails or toenails which easily crack or break.
- ☑ Indigestion, dehydration, hiccups.
- ☑ Aches and pain in the muscles, joints, bone, hands and feet.
- ☑ Sore, red, gritty eyes (conjunctivitis), blurred vision, stuffy or runny nose.

Continue to the next page

Statement of health professional

Patient identifier/label

Occasional risks continued:

- ☑ High blood pressure, excessive sweating, flushing.
- ☑ Difficulty sleeping, drowsiness, feeling sad or anxious, risk of falls.
- ☑ Tummy pain and diarrhoea caused by inflammation of the gut or pancreas.
- ☑ Oxaliplatin may temporarily affect the area around the voice box. This can feel as if it's difficult to swallow or to breathe.
- ☑ Increased risk of bleeding with this treatment. Symptoms include coughing up or vomiting blood, blood in your urine or bowels, or black, tarry stools.
- ☑ Cancer and treatment for cancer can increase your risk of developing a blood clot (thrombosis). A blood clot may cause pain, skin colour changes, swelling in a leg, breathlessness, chest pain. Tell your doctor straight away if you have any of these symptoms.
- ☑ A risk of tumour lysis syndrome (when treatment destroys cancer cells too quickly for the kidneys to cope). You may be prescribed medicines for prevention or treatment. Rarely, dialysis may be needed.

Other risks:

- ☑ Any drug given through a vein may leak out the vein and some may damage tissue around it while being given (extravasation). Leaks may cause stinging, pain, skin colour changes, swelling by the vein. Tell the nurse straight away if you have any of these symptoms. It's uncommon but important to deal with quickly.
- ☑ Before treatment, you will have blood tests to check for viruses (Hepatitis B, Hepatitis C, HIV or more unusual infections). This treatment may weaken your natural defence (immune) system making you prone to infections, or, existing infections could worsen or become active again if you've had them in the past. You may be given medicines to prevent or treat infection.
- ☑ Swelling of the spinal cord is uncommon with Glofitamab causing muscle weakness and numbness.
- ☑ Muscle breakdown (rhabdomyolysis) with Oxaliplatin is rare, but can be very serious and potentially lead to kidney damage. Tell your doctor right away if you notice any symptoms like severe muscle pain, weakness, or swelling, or if your urine looks dark (like tea or cola).

Other risks continued:

- ☑ This treatment rarely causes lung changes and haemolytic uraemic syndrome (HUS). HUS destroys cells which help with clotting, causing anaemia and kidney failure. Symptoms include bloody diarrhoea, tummy pain, bloating or cramping.
- ☑ Gemcitabine may very rarely cause a nervous system effect (posterior reversible encephalopathy syndrome or PRES) causing seizures, headache, changes in mental status and visual disturbances.
- ☑ Gemcitabine rarely causes severe skin reactions (Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis) causing sore patches which blister and peel.
- ☑ Hearing changes are rare.
- ☑ Changes in memory, concentration, ability to think clearly. There can be many causes, including your treatment, diagnosis or both.
- ☑ Some Gemcitabine products may contain alcohol. This may affect your ability to drive or operate machinery. If this is a problem, tell your doctor, nurse or pharmacist.
- ☑ Growth factor injections (G-CSF) given to maintain white blood cells and reduce infection risk. They may cause bone pain, headaches, itchy skin around the injection site.
- ☑ Complications of treatment can occasionally be severe and need intensive care support, or be life-threatening and result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.
- ☑ Following treatment, the lymphoma may either persist (rarely), or return after a period of time. Different treatment may then be needed if this is appropriate for you.

If applicable:

- ☑ Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
- ☑ Some anti-cancer medicines may damage the development of a baby in the womb or cause problems with pregnancy and birth. It is important not to become pregnant or make someone pregnant during treatment and for 6 months after. Use effective contraception throughout.

Statement of health professional

Patient identifier/label

Any other risks and information:

_____

_____

☑ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☑ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☑ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☑ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☑ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☑ Information leaflet for Glofitamab and GemOx (Gemcitabine and Oxaliplatin)

☑ 24 hour alert card or SACT advice service contact details

☑ SACT treatment record (cruk.org/treatment-record)

☑ Patient bispecific alert card

☐ Other, please state: _____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed: _____ Date: _____

Name (PRINT): _____ Job title: _____

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

☐ I have had enough time to consider my options 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 unable to sign but has indicated their consent.

Patient's signature: _____

Name (PRINT): _____ Date: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ Date: _____

Copy accepted by patient: yes / no (please circle)

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: _____

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign and date here)

Signed: _____

Date: _____

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 more information.

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.

The project is supported by Cancer Research UK. This does not mean you are 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/about-cancer/treatment/drugs
3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form