# Patient agreement to systemic anti-cancer therapy (SACT)

# Lenvatinib

	NHS number: (or other identifier)  Special requirements: (e.g. other language/other communication method)	
Hospital/NHS Trust/NHS Board:		
Responsible consultant:		
Name:		
Job title:		
Name of proposed course of treatment (in	clude brief explanation if medical term not clear)	
☐ Lenvatinib for the treatment of iodine refractory	differentiated thyroid cancer.	
Lenvatinib is taken orally once a day, treatment	t is supplied every 28 days (1 cycle).	
☐ Treatment is continued until disease progression	on or unacceptable side effects.	
Where will I have treatment?		
☐ Outpatient ☐ Day unit/case ☐ Inpatient	:	
	<del></del>	
Statement of health professi	onal	
•	ate 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 conse		
☐ I have explained the course of treatment and in	ntended benefit to the patient.	
The intended benefits (there are no guarantee	es about outcome)	
☐ Curative – to give you the best possible chance	e of being cured.	
☐ Disease control or palliative – the aim is not to both quality of life and survival.	cure, but to control or shrink the disease and improve	
☐ Adjuvant – therapy given after surgery or radio	otherapy to reduce the risk of the cancer coming back	
Neo-adjuvant – therapy given before surgery of and reduce the risk of the cancer coming back	or radiotherapy to shrink the cancer, allow treatment	

**Patient details** 

Patient's surname/family name:

Patient's first name(s):

## 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  High blood pressure.  Diarrhoea, loss of appetite, weight loss, feeling sick (nausea), being sick (vomiting), tummy pain, indigestion, constipation.  Sore mouth and ulcers, taste changes, dry mouth, hoarse voice.  Protein in the urine (picked up in urine test).  Sore hands and feet (sometimes change in colour, peeling on the palms of hands and soles of feet), skin rash, hair thinning or loss.  Muscle and joint pain, including in your back, hands and feet.  Tiredness and feeling weak (fatigue), fluid build-up in hands and feet.  Dizziness, headache, difficulty sleeping,	<ul> <li>□ Very rarely, Lenvatinib can cause posterior reversible encephalopathy syndrome (PRES), a serious effect on the brain. If this happens, you might experience seizures, headaches, changes in how you think, your behavious or problems with your vision. Inform your doctor straight away if you notice any of these.</li> <li>□ Risk of developing jaw problems (osteonecrosis) when treated with Lenvatinib. This is when healthy bone tissue in the jaw becomes damaged and dies. Gum disease, problems with your dentures, and some dental treatments (such as having a tooth removed) can increase the risk of this. Please see your dentist before starting Lenvatinib.</li> <li>□ Levantinib may slow wound healing. You may be</li> </ul>
sometimes low blood pressure.  Increase risk of infection from a drop in white blood cells (neutropenia), especially urinary tract infections.  Bruising and/or bleeding (sometimes including haemorrhage) due to low platelets.  Changes in liver and kidney function (monitored with blood tests). Kidney and liver failure less common.  Changes in electrolyte levels e.g. low calcium, potassium, magnesium, increase in cholesterol levels (monitored with blood tests).  Underactive thyroid causing low thyroid levels (monitored with blood tests).	asked to stop Lenvatinib before an operation or any procedures.  I confirm I will inform my doctor or nurse before I start a new medication or plan a surgical (including dental) procedure.  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.  Changes in your memory, concentration or ability to think clearly due to many causes.
Occasional side effects: Affecting between 1-10 in every 100 (1-10%) people	Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal
<ul> <li>□ Abnormal heart rhythm, changes in heart function causing heart problems such risk of a heart attack and heart failure.</li> <li>□ Cancer and treatment for cancer can increase your risk of developing a blood clot (thrombosis). A blood clot may cause pain, redness, skin colour changes, swelling in a leg, or breathlessness, chest pain. Tell your doctor straight away if you these symptoms.</li> <li>□ Increased risk of a stroke.</li> <li>□ Lenvatinib can sometimes cause holes (perforations) or abnormal tunnels (fistulas) in your digestive system and in other parts of your body (such as your lungs). In rare cases, these can be life-threatening leading to serious infections and bleeding.</li> <li>□ Dehydration, thickening of the skin, passing wind (flatulence).</li> </ul>	dryness).  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 forat least 1 month afterwards. Lenvatinib may affect how well hormonal contraceptives work. Use effective contraception throughout. Speak to your doctor or nurse.  Complications of treatment can very occasionally be life-threatening and may 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.

To be retained in patient notes Prepared by Pharmacist: Alia Nizam Checked by Pharmacist: Neil Masters Checked by Consultant: Jonathan Wadsley Date of issue: Aug-25; Version 2; Review date: Aug-28 Approved by: Adam Januszewski UK SACT Board Check cruk.org/sact\_consent for latest version **Lenvatinib** 

# Statement of health professional

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Patient	IMANTITIAN	IDDL

☐ 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 ma	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 importan	ce to the patient in regard to treatment
(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 Lenvatinib	l Signed.
☐ Information leaflet for Lenvatinib	
	Date:
☐ 24 hour alert card or SACT advice service contact details ☐ SACT treatment record	Date:Name (PRINT):
☐ 24 hour alert card or SACT advice service contact details ☐ SACT treatment record	Date:Name (PRINT):
24 hour alert card or SACT advice service contact details  SACT treatment record (cruk.org/treatment-record)	Date: Name (PRINT): Job title:
☐ 24 hour alert card or SACT advice service contact details ☐ SACT treatment record (cruk.org/treatment-record) ☐ Other, please state:	Date: Name (PRINT): Job title:
□ 24 hour alert card or SACT advice service contact details □ SACT treatment record (cruk.org/treatment-record) □ Other, please state:  Statement of interpreter (where approximately service)	Date: Name (PRINT): Job title:
□ 24 hour alert card or SACT advice service contact details □ SACT treatment record (cruk.org/treatment-record) □ Other, please state: □ Statement of interpreter (where applicable): I have interpreted the information above to the patient	Date: Name (PRINT): Job title:  opropriate)
☐ 24 hour alert card or SACT advice service contact details ☐ SACT treatment record (cruk.org/treatment-record) ☐ Other, please state:	Date: Name (PRINT): Job title:  opropriate)

# Statement of patient

Patient identifier/label

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 option	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	ture:
	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	Further information for patients  Contact details (if patient wishes to discuss options later):
have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.  Signed:	Contact your hospital team if you have any questions about cancer and its treatment.
Date: Name (PRINT): Job title:	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.
<ul><li>☐ See also advance decision to refuse treatment</li><li>☐ Patient has withdrawn consent (ask patient to sign and date here)</li></ul>	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

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