Health Technology Briefing
July 2025

Surovatamig for the treatment of relapsed or refractory diffuse large B-cell lymphoma after 2 or more treatments

Company/Developer	AstraZeneca

☒ New Active Substance ☐ Significant Licence Extension (SLE)

NIHRIO ID: 40138	NICE ID: Not available	UKPS ID: 674755

Licensing and Market Availability Plans

In phase III clinical development.

Summary

Surovatamig is in clinical development for the treatment of relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL) in adult patients who have received at least two prior lines of therapies. DLBCL is the most common type of non-Hodgkin lymphoma, a cancer caused by the build-up of abnormal B-cells (cells that form part of the immune system). The abnormal B-cells are larger than healthy B-cells and build up in the lymph nodes or other organs. The most common symptom is one or more painless swellings in the neck, armpit, and groin. These swellings are enlarged lymph nodes. Other general symptoms include heavy sweating at night, high temperatures that come and go with no obvious cause and losing a lot of weight. Whilst most patients respond to first line treatment, some patients have r/r disease (disease which returns following treatment or disease which does not respond to treatment). Treatment options for patients with r/r DLBCL are limited, and some of these treatments are associated with serious side effects including damage to the nervous system.

Surovatamig works by connecting T cells, which are part of the immune system, and cancerous B-cells. This enables the T-cells to find and destroy the cancerous B-cells. Surovatamig only weakly binds to the T cells, which reduces the risk of serious side effects such as increased inflammatory response and nervous system damage. Surovatamig is administered via intravenous infusion. If licensed, surovatamig would offer a new treatment option for patients with r/r DLBCL.

Proposed Indication

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.

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Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) in adult patients who have received at least two prior lines of therapies.[1]

Technology

Description

Surovatamig (AZD0486, TNB-486) is a IgG4 fully human CD19xCD3 bispecific T-cell engager (TCE).[1-3] Surovatamig binds to CD3 antigen on cytotoxic T lymphocytes, and CD19 antigen expressed on malignant B cells. This activates and redirects cytotoxic T lymphocytes to CD19-expressing tumour cells, resulting in T lymphocyte-mediated killing of tumour cells.[3] Surovatamig is designed to bind CD3 with low affinity, which helps reduce cytokine release during T cell activation. Despite its low affinity binding, surovatamig still enables T cells to target and kill malignant B cells.[2]

Surovatamig is in phase II clinical development for r/r DLBCL in adult patients who have received at least two prior lines of therapy.[1] In the phase II trial, SOUNDTRACK-B, surovatamig is administered via intravenous infusion.[1] The dosing regime is currently unknown.

Key Innovation

R/r DLBCL is associated with poor prognosis, when left untreated life expectancy for patients with r/r DLBCL is 3-4 months.[4,5] There are currently limited third-line treatment options available for patients with r/r DLBCL, with current available treatments providing poor patient outcomes.[6] Current CD19 targeting therapies for DLBCL have good efficacy, but are associated with serious side effects including cytokine release syndrome and neurotoxicity. Surovatamig induces tumour cell lysis with minimal cytokine release, meaning it is less likely to cause these dangerous side effects.[7] Surovatamig's low cytokine release profile may provide a wider therapeutic window compared to other bispecific TCEs in development, with a more favourable dosing regimen due to its longer half-life.[7] If licensed, surovatamig would offer a new treatment option for patients with r/r DLBCL who have limited, well-tolerated treatment options available.

Regulatory & Development Status

Surovatamig does not currently have Marketing Authorisation in the EU/UK for any indication.

Surovatamig is in phase II/III development for:[8]

- Follicular lymphoma
- Mature B-cell malignancies
- B-cell acute lymphoblastic leukaemia

Patient Group

Disease Area and Clinical Need

DLBCL, the most common non-Hodgkin lymphoma subtype, accounts for 25% to 45% of all NHL cases worldwide.[9] DLBCL develops when the body makes abnormal B lymphocytes, so it is a type of B-cell lymphoma. The abnormal lymphocytes build up in the lymph nodes or other body organs. This type of lymphoma has abnormal B cells that are larger than normal healthy B cells, and cancer cells in a spread out pattern (diffuse) rather than being grouped together. The most common symptom is one or more painless swellings in the neck, armpit, and groin. These swellings are enlarged lymph nodes. Other general symptoms include heavy sweating at night, high temperatures that come and go with no obvious cause

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and losing a lot of weight (more than one-tenth of the total weight).[10] Whilst most patients respond to first line treatment, approximately 40% of patients will have relapsed or refractory disease (disease which returns following treatment or disease which does not respond to treatment), most of these patients will die from DLBCL.[11]

Approximately 40% of non-Hodgkin lymphoma cases are DLBCL. In the UK between 2017-2019 there were 5,426 estimated new cases and 1,960 estimated deaths due to DLBCL.[10,12] In England, between 2023-2024, there were 36,557 finished consult episodes (FCE) for DLBCL, resulting in 26,188 day cases and 88,129 FCE bed days.[13]

Recommended Treatment Options

The National Institute for Health and Care Excellence (NICE) recommends the following treatments for third line treatment of r/r DLBCL:[14-18]

- Polatuzumab vedotin
- Rituximab
- Bendamustine
- Tafasitamab
- Lenalidomide
- Glofitamab
- Loncastuximab tesirine
- Epcoritamab

Clinical Trial Information

Trial	**SOUNDTRACK-B; NCT06526793;** A Modular Phase 2, Single-arm, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of AZD0486 in Participants With Relapsed or Refractory (R/R) B-cell Non-Hodgkin Lymphoma (SOUNDTRACK-B) **Phase II –** Recruiting **Locations:** United Kingdom, 6 EU countries, United States, Canada and other countries **Primary completion date (estimated):** March 2027
Trial Design	Non-randomised, sequential assignment, open-label
Population	N (estimated) = 240. Subjects with relapsed or refractory follicular lymphoma (FL) or DLBCL after 2 prior therapies: aged 18 to 80 years old.
Intervention(s)	Surovatamig administer via intravenous infusion.
Comparator(s)	No comparator.
Outcome(s)	Primary Outcomes: • Overall Response Rate (ORR), defined as the proportion of participants achieving either a partial response or complete response based on Lugano 2014 response criteria for non-Hodgkin Lymphoma, as determined by central review {Time frame: from first dose to end of treatment or data cutoff, whichever comes first, assessed up to about 12 months} For full list of other outcomes see trial record.

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Results (efficacy)	-
Results (safety)	-

Estimated Cost

The cost of surovatamig is not yet known.

Relevant Guidance

NICE Guidance

- NICE technology appraisal in development. Zamtocabtagene autoleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more therapies. (GID-TA11050). Expected date of publication to be confirmed.
- NICE technology appraisal. Epcoritamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments. (TA954). March 2024.
- NICE technology appraisal. Loncastuximab tesirine for treating relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma after 2 or more systemic treatments. (TA947). January 2024.
- NICE technology appraisal. Glofitamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments. (TA927). October 2023.
- NICE technology appraisal. Tafasitamab with lenalidomide for treating relapsed or refractory diffuse large B-cell lymphoma (TA883). May 2023.
- NICE technology appraisal. Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies. (TA872). February 2023.
- NICE technology appraisal. Polatuzumab vedotin with rituximab and bendamustine for treating relapsed or refractory diffuse large B-cell lymphoma (TA649). September 2020.
- NICE technology appraisal. Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies (TA567). March 2019.
- NICE technology appraisal. Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies (TA559). January 2019.
- NICE clinical guideline. Non-Hodgkin's lymphoma: diagnosis and management (NG52). July 2016
- NICE quality standard. Haematological cancers. (QS150). June 2017.

NHS England (Policy/Commissioning) Guidance

- NHS England. 2013/14. NHS Standard Contract for Cancer: Chemotherapy (Adult). B15/S/a
- NHS England. 2017. Clinical commissioning policy: Second allogeneic haematopoietic stem cell transplant for relapsed disease (all ages). 16068/P

Other Guidance

- NHS Hull University Teaching Hospitals. Hull University Teaching Hospitals and North Lincolnshire NHS Trusts: Haematology Multidisciplinary Team Guideline and Pathway: Diffuse Large B-cell Lymphoma. 2019.[19]
- H. Tilly, M. Gomes da Silva, U. Vitolo, A. Jack, M. Meignan, *et al*. Diffuse Large B-Cell Lymphoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. 2015.[20]

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Additional Information

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