**SECTION 1. PATIENT INFORMATION**

Gender: ❒ M ❒ F

**SECTION 2. PATIENT ELIGIBILITY CRITERIA**

**Can a comparable or satisfactory alternative treatment be used?**

🞏 Yes (in this case, the patient should be treated with the alternative therapy and will not be eligible for named patient early access supply)

🞏 No, specify the medical rationale for the request: ..................................................................................

.................................................................................. ..................................................................................

.................................................................................. ..................................................................................

.................................................................................. ..................................................................................

**Can the patient be included in an ongoing clinical trial?**

🞏 Yes (in this case, the patient should be included in the clinical trial and will not be eligible for named patient early access supply)

🞏 No, specify the reason: ..................................................................................

| **Eligibility Criteria** | | |
| --- | --- | --- |
| **YES** | **NO** | **Please answer each question. The patient’s eligibility will then be checked, including that none of the non-eligibility criteria apply** |
| 🞏 | 🞏 | Patient aged 18 or over |
| 🞏 | 🞏 | Relapsed or refractory diffuse large B‑cell lymphoma (DLBCL) (including those arising from FL or HGBCL) and primary mediastinal large B‑cell lymphoma (PMBCL) after two or more lines of systemic therapy  Please select the exact diagnosis:  🞏 DLBCL  🞏 DLBCL arising from FL  🞏 HGBCL  🞏 PMBCL |
| 🞏 | 🞏 | No Evidence, suspicion or history of CNS involvement by the lymphoma |
| 🞏 | 🞏 | Eastern cooperative oncology group (ECOG) score ≤1 |
| 🞏 | 🞏 | No evidence of clinically significant active infection and no clinically significant cardiac dysfunction. |
| 🞏 | 🞏 | Normal renal, hepatic, and pulmonary criteria |
| 🞏 | 🞏 | In the physician’s judgment, the patient is in good general condition and fit enough to receive cell therapy |

| **Non-Eligibility Criteria** | | |
| --- | --- | --- |
| **YES** | **NO** | **Please answer each question. The patient’s eligibility will then be checked, including that none of the non-eligibility criteria apply** |
| 🞏 | 🞏 | History of Richter’s transformation of CLL |
| 🞏 | 🞏 | Prior CAR-T therapy |
| 🞏 | 🞏 | Fungal, bacterial, viral or other infection that is uncontrolled or requires the administration of IV treatments |
| 🞏 | 🞏 | Known history of infection with HIV or HBV (HBsAg positive) or HCV (Ac anti-HCV positive). A history of HBV or HCV is permitted if the viral load is undetectable by quantitative PCR and/or nucleic acid testing |
| 🞏 | 🞏 | History of central nervous system disorders such as epileptic seizures, cerebrovascular ischaemia / haemorrhage, dementia, cerebellar disease or any autoimmune disease with cerebral involvement |
| 🞏 | 🞏 | History of hypersensitivity to a treatment used under this EAP |
| 🞏 | 🞏 | Live attenuated vaccine ≤ 6 weeks prior to conditioning chemotherapy |

**SECTION 3. PATIENT MEDICAL HISTORY**

**CURRENT OR PREVIOUS TREATMENTS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **PRODUCTS or strategy** | **START DATE** | **STOP DATE** | **REASON FOR STOPPING**  **Assessment of response by the investigator when this line was stopped** |
| **1st line** | ............................  .............................  .............................  ............................. | ……../……../…….. | ……../……../…….. | ..................................................  ............................................... |
| **2nd line** | ............................  .............................  .............................  ............................. | ……../……../…….. | ……../……../…….. | ..................................................  ............................................... |
| **3rd line** | ............................  .............................  .............................  ............................. | ……../……../…….. | ……../……../…….. | ..................................................  ............................................... |
| **4th line and beyond** | ..............................  .............................  .............................  ............................. | ……../……../…….. | ……../……../…….. | .................................................  ............................................... |

**COMORBIDITIES:** 🞏 Yes - Fill in the table below 🞏 No

|  |  |  |
| --- | --- | --- |
| Comorbidity | Date of diagnosis  *(DD/MM/YYYY)* | Details |
|  | \_\_\_/\_\_\_/\_\_\_ |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  | \_\_\_/\_\_\_/\_\_\_ |  |
|  | \_\_\_/\_\_\_/\_\_\_ |  |
|  | \_\_\_/\_\_\_/\_\_\_ |  |
|  | \_\_\_/\_\_\_/\_\_\_ |  |
|  | \_\_\_/\_\_\_/\_\_\_ |  |

**LABORATORY PARAMETERS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Date** | **Result** | **Unit** | **Normal value** | **Cause if value is abnormal** |
| **Absolute lymphocyte count** | \_\_ / \_\_\_ / \_\_\_ | |\_\_|\_\_|\_\_|\_\_| | G/L | |\_\_|\_\_|\_\_|\_\_| |  |
| **CRP** | \_\_ / \_\_\_ / \_\_\_ | |\_\_|\_\_|\_\_|\_\_| | mg/L | |\_\_|\_\_|\_\_|\_\_| |  |

**SECTION 4. PHYSICIAN DECLARATION**

□ I confirm that I have signed a copy of the Prescriber Agreement provided to me by Gilead.

□ I confirm that I accept full legal liability and responsibility for the use of axicabtagene ciloleucelfor this patient under my care.

□ I understand that it is my responsibility to report adverse events ("AE") and special situations reports (“SSR”) in accordance with the Prescriber Agreement.

□ I confirm that I have obtained the patient consent using the Patient Acknowledgment Form.

|  |  |
| --- | --- |
| **Prescribing physician (PLEASE USE BLOCK CAPITALS)**  FULL NAME\*:  SPECIALTY:  INSTITUTION:  ADDRESS\*:  COUNTRY\*:  PROFESSIONAL DESIGNATION (e.g. MD)\*:  LICENCE NUMBER:  POSTCODE:  TOWN:  TELEPHONE\*:  FAX:  E-MAIL\*: | |
| **Physician’s signature**  SIGNATURE  Date\*: |\_\_|\_\_| |\_\_|\_\_| |\_\_|\_\_|\_\_|\_\_| | **Pharmacist’s signature**  SIGNATURE  Date\*: |\_\_|\_\_| |\_\_|\_\_| |\_\_|\_\_|\_\_|\_\_| |

\*MANDATORY FIELDS

|  |
| --- |
| **SECTION TO BE FILLED IN BY GILEAD** |
| **REQUEST FOR FURTHER INFORMATION**  ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| **DeCision**  **🞎 Request accepted – KITE KONNECT®** Patient ID number: ………………..  **🞎 Request refused**  Reason:………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………… |
| **Name:** ………………............................  **Date:** |\_\_|\_\_| |\_\_|\_\_| |\_\_|\_\_|\_\_|\_\_| **Signature** |