

INVESTIGATOR / CENTRE

Dr. P.J. Lugtenburg

PATIENT INITIALS

[][] [][]

DATE OF BIRTH

[][] / [][] [][] / [][]

PATIENTS SOURCE NUMBER

[][] [][] [][] [][]

GENDER

Male / Female

DATE INFORMED CONSENT

[][] [][] / [][] [][] [][] / 20[][] [][]

INCLUSIE CRITERIA

	YES	NO
1. Execute an informed consent.	<input type="checkbox"/>	<input type="checkbox"/>
2. Patients age ≥ 18 years at signing the informed consent.	<input type="checkbox"/>	<input type="checkbox"/>
3. Diagnosis of relapsed or refractory lymphoid malignancy for which there are no available therapies.	<input type="checkbox"/>	<input type="checkbox"/>
4. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 (Appendix A, Section 15.1).	<input type="checkbox"/>	<input type="checkbox"/>
5. Neutrophils $> 1,000 \mu\text{L}$	<input type="checkbox"/>	<input type="checkbox"/>
6. Platelets $\geq 75,000 \mu\text{L}$	<input type="checkbox"/>	<input type="checkbox"/>
7. Aspartate aminotransferase/alanine aminotransferase (AST/ALT) ≤ 2.5 upper limit of normal (ULN).	<input type="checkbox"/>	<input type="checkbox"/>
8. Total bilirubin $< 2.0 \text{ mg/dL}$ unless elevated due to known Gilbert's syndrome.	<input type="checkbox"/>	<input type="checkbox"/>
9. Creatinine $\leq 1.5 \text{ ULN}$.	<input type="checkbox"/>	<input type="checkbox"/>
10. Serum potassium and magnesium within normal range.	<input type="checkbox"/>	<input type="checkbox"/>
11. Males and females of child bearing potential, and their partners, must be willing to use at least two effective forms of birth control during the study drug administration and for at least ninety (90) days after the administration of the study drug to be eligible to participate. Vasectomized partners and patients must be willing to use a secondary method of effective birth control. Sexual abstinence is considered a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study treatment. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the patient.	<input type="checkbox"/>	<input type="checkbox"/>

INCLUSIE CRITERIA – ALLEEN voor cohort 2: relapsed/refractory Hodgkin's lymphoma

	YES	NO
1. At least three lines of prior therapy and no other standard therapy available with proven clinical benefit.	<input type="checkbox"/>	<input type="checkbox"/>

INCLUSIE CRITERIA – ALLEEN voor cohort 3: relapsed/refractory peripheral T-cell lymphoma (PTCL)

	YES	NO
1. Only PTCL patients with histologically or cytologically confirmed PTCL-NOS, AITL or ALCL.	<input type="checkbox"/>	<input type="checkbox"/>
2. At least one line of prior combination therapy and no other standard therapy available with proven clinical benefit.	<input type="checkbox"/>	<input type="checkbox"/>

INCLUSIE CRITERIA – ALLEEN voor cohort 4: relapsed/refractory cutaneous T-cell lymphoma (CTCL), subtypes mycosis fungoides (MF) en Sézary Syndrome (SS)

	YES	NO
1. Only CTCL patients with histologically or cytologically confirmed MF or SS with stage IIb to IVb disease based on modified ISCL/EORTC staging.	<input type="checkbox"/>	<input type="checkbox"/>
2. At least one line and a maximum of four prior standard systemic therapies and no other standard therapy available with proven clinical benefit.	<input type="checkbox"/>	<input type="checkbox"/>

INCLUSIE CRITERIA – ALLEEN voor cohort 5: relapsed/refractory T-cell Prolymphocytic leukemia (T-PLL)		
	YES	NO
1. A maximum of two lines of prior therapy and no other standard therapy available with proven clinical benefit. Patients ineligible for treatment with alemtuzumab can be included.	<input type="checkbox"/>	<input type="checkbox"/>

EXCLUSIE CRITERIA		
	YES	NO
1. Patients with any central nervous system (CNS) involvement	<input type="checkbox"/>	<input type="checkbox"/>
2. Diagnosis of acute leukemia or any patient that has been treated with fludarabine.	<input type="checkbox"/>	<input type="checkbox"/>
3. Any patient who has relapsed within 100 days of stem cell infusion following an allogenic or autologous bone marrow transplant.	<input type="checkbox"/>	<input type="checkbox"/>
4. Patients with QTc interval > 450 msec at baseline.	<input type="checkbox"/>	<input type="checkbox"/>
5. Patients who are on treatment with drugs known to prolong the QT/QTc interval. Refer to CredibleMeds list of drugs with known risk of Torsade des pointes (TdP): https://crediblemeds.org/new-drug-list	<input type="checkbox"/>	<input type="checkbox"/>
6. Any serious medical condition that interferes with adherence to trial procedures.	<input type="checkbox"/>	<input type="checkbox"/>
7. Patients with a history of a second malignancy diagnosed within three (3) years of trial enrollment excluding basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or in situ cervical cancer that has undergone potentially curative therapy.	<input type="checkbox"/>	<input type="checkbox"/>
8. Pregnant or breast feeding females.	<input type="checkbox"/>	<input type="checkbox"/>
9. New York Heart Association (NYHA) stage III/IV congestive heart failure. The following arrhythmias: atrial fibrillation/flutter with poor rate control, documented sustained ventricular tachycardia (defined as >30 seconds or requiring cardioversion before 30 seconds have elapsed) or TdP.	<input type="checkbox"/>	<input type="checkbox"/>
10. Active infections, or other significant co-morbidities (e.g., active central nervous system metastases and/or carcinomatous meningitis, active infection requiring systemic therapy, history of human immunodeficiency virus (HIV) infection, or active Hepatitis B or Hepatitis C).	<input type="checkbox"/>	<input type="checkbox"/>
11. Previous cancer therapies within four (4) weeks or 5 half-lives, whichever is shorter, of dosing unless the patient has recovered to eligibility levels prior to treatment in this study.	<input type="checkbox"/>	<input type="checkbox"/>
12. Use of other investigational agents within 30 days or 5 half-lives prior to the first dose of study drug unless patient has recovered from any related toxicities ≥ Grade 1.	<input type="checkbox"/>	<input type="checkbox"/>
13. Steroid treatment within seven (7) days prior to study treatment. Patients that require intermittent use of bronchodilators, topical steroids or local steroid injections will not be excluded from the trial. Patients who have been stabilized to 10 mg PO QD or less seven (7) days prior to trial drug administration are allowed.	<input type="checkbox"/>	<input type="checkbox"/>
14. Patients on Valproic Acid for any indication (epilepsy, mood disorder) must be excluded from the trial or must stop using the medication and have a wash out period of 3.5 days prior to first dose of EDO-S101 (C1D1).	<input type="checkbox"/>	<input type="checkbox"/>

Checked by: _____ Signature _____

Date of registration: _____