NOVARTIS

CHECKLIST FOR VERIFICATION OF

INCLUSION & EXCLUSION CRITERIA

Protocol Identification:	**CCTL019G2201J**	**Patient No.:**	
Site Number:		**Patient Initials (if permitted):**	

No.	Inclusion Criterion	Checked?	Comment
1.	CD19 expressing (in peripheral blood or bone marrow by flow cytometry) B-cell Acute Lymphoblastic Leukemia	☐	
2.	De novo NCI HR B-ALL who received first-line treatment and are MRD ≥ 0.01% at EOC as per Amended Protocol (Version 1.0) Section 5.2. EOC bone marrow MRD will be collected prior to screening and will be assessed by multi-parameter flow cytometry using central laboratory analysis	☐	
3.	Age 1 to 25 years at the time of screening	☐	
4.	Lansky (age < 16 years) or Karnofsky (age ≥ 16 years) performance status ≥ 60% at screening	☐	
5.	Adequate organ function during the screening period *as per Protocol Section 5.2*	☐	
6.	Prior induction and consolidation chemotherapy allowed as per Amended Protocol (Version 1.0) Section 5.2 and Appendix 3	☐	
7.	Signed written informed consent and assent forms, if applicable, must be obtained prior to any study procedures	☐	
8.	Must meet the institutional criteria to undergo leukapheresis	☐	
9.	Once all other eligibility criteria are confirmed, must have a leukapheresis product of nonmobilized cells received and accepted by the manufacturing site. NOTE: Leukapheresis product will not be shipped to or assessed for acceptance by the manufacturing site until documented IRT confirmation of all other clinical eligibility criteria is received.	☐	

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1.	M3 marrow (≥ 25% blasts by morphologic criteria) at the completion of first-line induction therapy	☐	
2.	M2 (i.e. ≥ 5% blasts by morphologic criteria) or M3 marrow or Persistent extramedullary disease at the completion of first-line consolidation therapy or evidence of disease progression in the peripheral blood or new extramedullary disease prior to enrollment. Patients with previous CNS disease are eligible if there is no active CNS involvement of leukemia (defined as CNS-3 by NCCNv1 2018) at the time of screening	☐ ☐ ☐	
3.	Philadelphia chromosome positive (Ph+) ALL	☐	
4.	Hypodiploid: less than 44 chromosomes and/or DNA index < 0.81, or other clear evidence of a hypodiploid clone	☐	
5.	Prior tyrosine kinase inhibitor therapy	☐	
6.	Subjects with concomitant genetic syndromes associated with bone marrow failure states: such as subjects with Fanconi anemia, Kostmann syndrome, Shwachman syndrome or any other known bone marrow failure syndrome. Subjects with Down syndrome will not be excluded	☐	
7.	Subjects with Burkitt's lymphoma/leukemia as per Protocol Section 5.3	☐	
8.	Prior malignancy, except carcinoma *in situ* of the skin or cervix treated with curative intent and with no evidence of active disease	☐	
9.	Subject has had treatment with any prior anti-CD19 therapy	☐	
10.	Treatment with any prior gene or engineered T cell therapy	☐	
11.	Clinically significant active infection confirmed by clinical evidence, imaging, or positive	☐	

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No.	Exclusion Criterion	Checked?	Comment
	laboratory tests (e.g., blood cultures, PCR for DNA/RNA, etc.)		
12.	**Presence of active hepatitis B or C as per Amended Protocol (Version 1.0) Section 5.3 and Appendix 3**	☐	

No.	Exclusion Criterion	Checked?	Comment
13.	**Human Immunodeficiency Virus (HIV) positivity as indicated by serology. Serology must be repeated, if the interval between testing at screening and tisagenlecleucel infusion exceeds 8 weeks**	☐	
14.	**Subject had an investigational medicinal product within the last 30 days prior to screening. NOTE: Investigational therapies must not be used at any time while on study until the first relapse following tisagenlecleucel infusion**	☐	
15.	**Exclusionary medications prior to subject infusion as per Amended Protocol (Version 1.0) Section 5.3.**	☐	
16.	**Pregnant or nursing (lactating) women.** **NOTE: Women of child-bearing potential must have a negative serum pregnancy test performed within 24 hours before leukapheresis, lymphodepletion, and prior to tisagenlecleucel infusion.**	☐	
17.	**<u>Women of child-bearing potential</u> (defined as all women physiologically capable of becoming pregnant) unless they agree to use highly effective methods of contraception from enrolment through at least 12 months after the tisagenlecleucel infusion and until CAR-T cells are no longer present by qPCR on two consecutive tests. qPCR test results will be available upon request. Please refer to Amended Protocol (Version 1.0) Section 5.3 for additional information.**	☐	
18.	**<u>Sexually active males</u> must use a condom during intercourse from enrollment and for at least 12 months after the tisagenlecleucel infusion and until CAR T-cells are no longer**	☐	

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	present by qPCR on two consecutive tests. qPCR test results will be available upon request. Please refer to Amended Protocol (Version 1.0) Section 5.3 for additional information.		

SCREENING VISIT:

Herewith I confirm that I checked the inclusion and exclusion criteria as specified above and I verified the criteria assessable at today's visit against the source documents of the patient.

The patient is eligible for study participation at this visit:			**YES** ☐	**NO** ☐
Checklist completed by:		**Date of completion:**		
Signature:				

Patient eligibility visit:

Herewith I confirm that I rechecked the inclusion and exclusion criteria as specified above and I verified all criteria against the source documents of the patient.

The patient is still eligible for study participation at this visit:			**YES** ☐	**NO** ☐
Checklist completed by:		**Date of completion:**		
Signature:				