Nonconforming Lisocabtagene Maraleucel Expanded Access Protocol

Status: OPEN TO ACCRUAL

Eligibility Criteria

Age: 18 years and over
Healthy Volunteers:

Inclusion Criteria:

1. Subject and/or LAR must understand and voluntarily sign an informed consent form prior to any study-related assessments/procedures being conducted. 2. Subject has relapsed and/or refractory large B-cell lymphoma and is, per the treating physician assessment, eligible for treatment with lisocabtagene maraleucel per the approved prescribing information. 3. Subject is ? 18 years of age at the time of signing the informed consent form. 4. Subject had a specific batch of lisocabtagene maraleucel manufactured intended for commercial treatment; however, the final manufactured product did not meet commercial release criteria. 5. Remanufacturing (eg, repeat leukapheresis and manufacturing) is deemed not feasible or clinically inappropriate per assessment of the treating physician in discussion with the subject. 6. Subject is clinically stable, has recovered from any toxicities prior to receiving lymphodepleting chemotherapy, and has adequate bone marrow function to receive lymphodepleting chemotherapy. The treating physician is advised to contact Medical Monitor in the event there is any concern regarding administration of lymphodepleting chemotherapy. 7. Females of childbearing potential must: 1. Have a negative pregnancy test as verified by the treating physician within 7 days prior to the first dose of lymphodepleting chemotherapy following institutional testing methodology practices. This applies even if the subject practices true abstinence from heterosexual contact. 2. Either commit to true abstinence from heterosexual contact or agree to use, and be able to comply with, effective contraception without interruption. Contraception methods must include 1 highly effective method from screening until at least 12 months after the nonconforming lisocabtagene maraleucel administration. 3. Agree to abstain from breastfeeding during study participation and for at least 12 months following nonconforming lisocabtagene maraleucel administration. 4. There are insufficient exposure data to provide any recommendation concerning the duration of contraception and the abstaining from breastfeeding following treatment with lisocabtagene maraleucel. Any decision regarding contraception and breastfeeding after infusion should be discussed with the treating physician. 8. Male subjects must: 1. Practice true abstinence or agree to use a condom during sexual contact with a pregnant female or a female of childbearing potential for at least 12 months after nonconforming lisocabtagene maraleucel administration even if the subject has undergone a successful vasectomy. 2. There are insufficient exposure data to provide any recommendation concerning the duration of contraception following treatment with lisocabtagene maraleucel. Any decision regarding contraception after infusion should be discussed with the treating physician 9. Subject must agree to not donate blood, organs, tissue, sperm or semen and egg cells for usage in other individuals for at least 1 year following nonconforming lisocabtagene maraleucel administration.

Exclusion Criteria:

1. Subject has a hypersensitivity to the active substance or to any of the excipients. 2. Subject should not experience a significant worsening in clinical status that would, in the opinion of the treating physician, either increase the risk of adverse events associated with lymphodepleting chemotherapy, or exclude them from treatment with nonconforming lisocabtagene maraleucel. 3. Subject has any significant medical condition, laboratory abnormality, or psychiatric illness, sociologic or geographic condition that would prevent the subject from participating in the Expanded Access Protocol complying with protocol requirements in the Investigator's judgement. 4. Subject has any condition and/or laboratory abnormality that places the subject at unacceptable risk if he/she were to participate in the Expanded Access Protocol based on the Investigator's judgement 5. Pregnant or nursing women or has intention of becoming pregnant during the study. 6. Subjects with central nervous system (CNS)-only involvement by malignancy (note: subjects with secondary CNS involvement are allowed on study). 7. Subject has active hepatitis B, hepatitis C, or human immunodeficiency virus (HIV) infection at the time of pretreatment evaluation 8. Subject has uncontrolled systemic fungal, bacterial, viral or other infection despite appropriate antibiotics or other treatment at the time of nonconforming lisocabtagene maraleucel administration. 9. Subject has presence of acute or chronic graft-versus-host disease (ie, GVHD) 10. Use of the following: 1. Therapeutic doses of corticosteroids (defined as > 20 mg/day prednisone or equivalent) within 72 hours prior to nonconforming lisocabtagene maraleucel administration. Physiologic replacement, topical, and inhaled steroids are permitted. 2. Low dose chemotherapy (eg, vincristine, rituximab, cyclophosphamide ? 300 mg/m2)given after leukapheresis to maintain disease control must be stopped ? 7 days prior to lymphodepleting chemotherapy. 3. Cytotoxic chemotherapeutic agents that are not considered lymphotoxic (see below) within 1 week of LD chemotherapy. Oral chemotherapeutic agents, including lenalidomide and ibrutinib, are allowed if at least 3 half-lives have elapsed prior to lymphodepleting chemotherapy. 4. Donor lymphocyte infusions within 6 weeks of nonconforming lisocabtagene maraleucel administration.

Conditions & Interventions

Interventions:
Biological: Nonconforming Lisocabtagene Maraleucel
Conditions:
Lymphoma, Large B-Cell, Diffuse
Keywords:
Expanded Access, JCAR017, Lisocabtagene Maraleucel, CAR T, nonconforming,, relapsed/refractory diffuse large B cell lymphoma, nonconforming lisocabtagene mareleucel

More Information

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