EAP for subjects receiving Idecabtagene Vicleucel That is Nonconforming for Commercial Release

Status: OPEN TO ACCRUAL

Eligibility Criteria

Age: 18 years and over
Healthy Volunteers:

Inclusion Criteria:

• Had a participant-specific batch of Idecabtagene vicleucel (ide-cel) manufactured intended for commercial treatment; however, the final manufactured product was nonconforming and did not meet commercial release criteria

• Remanufacturing is deemed not feasible or clinically inappropriate per assessment of the treating physician in discussion with the participant

• Clinically stable

Exclusion Criteria:

• Has a hypersensitivity to the active substance or to any of the excipients

• No experience of 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 Idecabtagene vicleucel (ide-cel)

• Has any condition and/or laboratory abnormality that places the participant at unacceptable risk if he/she were to participate in the Expanded Access Protocol based on the Investigator's judgement Other protocol-defined inclusion/exclusion criteria apply

Conditions & Interventions

Interventions:
Biological: Nonconforming idecabtagene vicleucel, drug: Idecabtagene vicleucel, Modality: Immunotherapy
Conditions:
Multiple Myeloma
Keywords:
BB2121, Multiple Myeloma, Expanded Access, idecabtagene vicleucel, nonconforming, CAR T, EAP, Pre-Approval Access

More Information

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