

You are invited to join us for an educational program focusing on:

Breyanzi®: CAR T Cell Therapy for Second-line LBCL

TOPICS WILL ADDRESS:

- The mechanism of action of Breyanzi, a CAR T cell therapy
- The latest clinical data for Breyanzi in second-line large B-cell lymphoma (LBCL) in both transplant-eligible and -ineligible patients
- How to assess eligibility for Breyanzi and navigate the selection and referral process

Meeting Date: Friday, April 26, 2024

Meeting Time: 6:00 PM - EST

FEATURING:

Kristin Martin, MSN, RN, OCN
Clinical Nurse Consultant
Bristol Myers Squibb

LOCATION:

Del Frisco's
The Wine Cellar
950 I Street, NW
Washington, District Of Columbia



TO REGISTER:

Please scan the QR code or visit <https://myattendeesource.com/BMS/240426-BMS-9>

or contact

NAME: Aaron Dread

EMAIL: aaron.dread@bms.com

or call

1-866-326-7600 during the hours of 8:30 am to 5:00 pm ET,
Monday–Friday, and refer to meeting ID 240426-BMS-97413

This is a promotional program, and no CME credits are offered.

Intended for specific recipients only; please do not forward or further disseminate.

INDICATION

BREYANZI is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:

- refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or
- refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or
- relapsed or refractory disease after two or more lines of systemic therapy.

LIMITATIONS OF USE: BREYANZI is not indicated for the treatment of patients with primary central nervous system lymphoma.

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITIES

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving BREYANZI. Do not administer BREYANZI to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab with or without corticosteroids.
- Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving BREYANZI, including concurrently with CRS, after CRS resolution or in the absence of CRS. Monitor for neurologic events after treatment with BREYANZI. Provide supportive care and/or corticosteroids as needed.
- BREYANZI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BREYANZI REMS.

Please see pages 2-3 for Important Safety Information for BREYANZI. Please click for full [Prescribing Information](#), including [Boxed WARNINGS](#) and [Medication Guide](#), or see full PI provided by the BMS representative.

IMPORTANT SAFETY INFORMATION

CYTOKINE RELEASE SYNDROME

Cytokine release syndrome (CRS), including fatal or life-threatening reactions, occurred following treatment with BREYANZI. Among patients receiving BREYANZI for LBCL (N=418), CRS occurred in 46% (190/418), including \geq Grade 3 CRS (Lee grading system) in 3.1% of patients.

In patients receiving BREYANZI after two or more lines of therapy for LBCL, CRS occurred in 46% (122/268), including \geq Grade 3 CRS in 4.1% of patients. One patient had fatal CRS and 2 had ongoing CRS at time of death. The median time to onset was 5 days (range: 1 to 15 days). CRS resolved in 98% with a median duration of 5 days (range: 1 to 17 days).

In patients receiving BREYANZI after one line of therapy for LBCL, CRS occurred in 45% (68/150), including Grade 3 CRS in 1.3% of patients. The median time to onset was 4 days (range: 1 to 63 days). CRS resolved in all patients with a median duration of 4 days (range: 1 to 16 days).

The most common manifestations of CRS ($\geq 10\%$) included fever (94%), hypotension (42%), tachycardia (28%), chills (23%), hypoxia (16%), and headache (12%).

Serious events that may be associated with CRS include cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), cardiac arrest, cardiac failure, diffuse alveolar damage, renal insufficiency, capillary leak syndrome, hypotension, hypoxia, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS).

Ensure that 2 doses of tocilizumab are available prior to infusion of BREYANZI.

Of the 418 patients who received BREYANZI for LBCL, 23% received tocilizumab and/or a corticosteroid for CRS, including 10% who received tocilizumab only and 2.2% who received corticosteroids only.

NEUROLOGIC TOXICITIES

Neurologic toxicities that were fatal or life-threatening, including immune effector cell-associated neurotoxicity syndrome (ICANS), occurred following treatment with BREYANZI. Serious events including cerebral edema and seizures occurred with BREYANZI. Fatal and serious cases of leukoencephalopathy, some attributable to fludarabine, also occurred.

In patients receiving BREYANZI after two or more lines of therapy for LBCL, CAR T cell-associated neurologic toxicities occurred in 35% (95/268), including \geq Grade 3 in 12% of patients. Three patients had fatal neurologic toxicity and 7 had ongoing neurologic toxicity at time of death. The median time to onset of neurotoxicity was 8 days (range: 1 to 46 days). Neurologic toxicities resolved in 85% with a median duration of 12 days (range: 1 to 87 days).

In patients receiving BREYANZI after one line of therapy for LBCL, CAR T cell-associated neurologic toxicities occurred in 27% (41/150) of patients, including Grade 3 cases in 7% of patients. The median time to onset of neurologic toxicities was 8 days (range: 1 to 63 days). The median duration of neurologic toxicity was 6 days (range: 1 to 119 days).

In all patients combined receiving BREYANZI for LBCL, neurologic toxicities occurred in 33% (136/418), including \geq Grade 3 cases in 10% of patients. The median time to onset was 8 days (range: 1 to 63), with 87% of cases developing by 16 days. Neurologic toxicities resolved in 85% of patients with a median duration of 11 days (range: 1 to 119 days). Of patients developing neurotoxicity, 77% (105/136) also developed CRS.

The most common neurologic toxicities ($\geq 5\%$) included encephalopathy (20%), tremor (13%), aphasia (8%), headache (6%), dizziness (6%), and delirium (5%).

CRS AND NEUROLOGIC TOXICITIES MONITORING

Monitor patients daily for at least 7 days following BREYANZI infusion at a REMS-certified healthcare facility for signs and symptoms of CRS and neurologic toxicities and assess for other causes of neurological symptoms. Monitor patients for signs and symptoms of CRS and neurologic toxicities for at least 4 weeks after infusion and treat promptly. At the first sign of CRS, institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids as indicated. Manage neurologic toxicity with supportive care and/or corticosteroid as needed. Counsel patients to seek immediate medical attention should signs or symptoms of CRS or neurologic toxicity occur at any time.

BREYANZI REMS

Because of the risk of CRS and neurologic toxicities, BREYANZI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BREYANZI REMS. The required components of the BREYANZI REMS are:

- Healthcare facilities that dispense and administer BREYANZI must be enrolled and comply with the REMS requirements.
- Certified healthcare facilities must have on-site, immediate access to tocilizumab.
- Ensure that a minimum of 2 doses of tocilizumab are available for each patient for infusion within 2 hours after BREYANZI infusion, if needed for treatment of CRS.
- Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer BREYANZI are trained on the management of CRS and neurologic toxicities.

Further information is available at www.BreyanziREMS.com, or contact Bristol-Myers Squibb at 1-888-423-5436.

Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving BREYANZI, including concurrently with CRS, after CRS resolution or in the absence of CRS. Monitor for neurologic events after treatment with BREYANZI. Provide supportive care and/or corticosteroids as needed.

BREYANZI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the BREYANZI REMS.

HYPERSENSITIVITY REACTIONS

Allergic reactions may occur with the infusion of BREYANZI. Serious hypersensitivity reactions, including anaphylaxis, may be due to dimethyl sulfoxide (DMSO).

IMPORTANT SAFETY INFORMATION (CONT'D)

SERIOUS INFECTIONS

Severe infections, including life-threatening or fatal infections, have occurred in patients after BREYANZI infusion.

In patients receiving BREYANZI for LBCL, infections of any grade occurred in 36% with Grade 3 or higher infections occurring in 12% of all patients. Grade 3 or higher infections with an unspecified pathogen occurred in 7%, bacterial infections occurred in 4.3%, viral infections in 1.9% and fungal infections in 0.5%.

Febrile neutropenia developed after BREYANZI infusion in 8% of patients with LBCL. Febrile neutropenia may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad spectrum antibiotics, fluids, and other supportive care as medically indicated.

Monitor patients for signs and symptoms of infection before and after BREYANZI administration and treat appropriately. Administer prophylactic antimicrobials according to standard institutional guidelines.

Avoid administration of BREYANZI in patients with clinically significant active systemic infections.

Viral reactivation: Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients treated with drugs directed against B cells.

In patients who received BREYANZI for LBCL, 15 of the 16 patients with a prior history of HBV were treated with concurrent antiviral suppressive therapy. Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing. In patients with prior history of HBV, consider concurrent antiviral suppressive therapy to prevent HBV reactivation per standard guidelines.

PROLONGED CYTOPENIAS

Patients may exhibit cytopenias not resolved for several weeks following lymphodepleting chemotherapy and BREYANZI infusion.

Grade 3 or higher cytopenias persisted at Day 29 following BREYANZI infusion in 36% of patients with LBCL and included thrombocytopenia in 28%, neutropenia in 21%, and anemia in 6%.

Monitor complete blood counts prior to and after BREYANZI administration.

HYPOGAMMAGLOBULINEMIA

B-cell aplasia and hypogammaglobulinemia can occur in patients receiving treatment with BREYANZI.

In patients receiving BREYANZI for LBCL, hypogammaglobulinemia was reported as an adverse reaction in 11% of patients.

Hypogammaglobulinemia, either as an adverse reaction or laboratory IgG level below 500 mg/dL after infusion, was reported in 28% of patients.

Monitor immunoglobulin levels after treatment with BREYANZI and manage using infection precautions, antibiotic prophylaxis, and immunoglobulin replacement as clinically indicated.

Live vaccines: The safety of immunization with live viral vaccines during or following BREYANZI treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during BREYANZI treatment, and until immune recovery following treatment with BREYANZI.

SECONDARY MALIGNANCIES

Patients treated with BREYANZI may develop secondary malignancies. Monitor lifelong for secondary malignancies. In the event that a secondary malignancy occurs, contact Bristol-Myers Squibb at 1-888-805-4555 for reporting and to obtain instructions on collection of patient samples for testing.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Due to the potential for neurologic events, including altered mental status or seizures, patients receiving BREYANZI are at risk for developing altered or decreased consciousness or impaired coordination in the 8 weeks following BREYANZI administration. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, for at least 8 weeks.

ADVERSE REACTIONS

The most common nonlaboratory adverse reactions (incidence $\geq 30\%$) are fever, CRS, fatigue, musculoskeletal pain, and nausea.

The most common Grade 3-4 laboratory abnormalities ($\geq 30\%$) include lymphocyte count decrease, neutrophil count decrease, platelet count decrease, and hemoglobin decrease.

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Please click for full [Prescribing Information](#), including [Boxed WARNINGS](#) and [Medication Guide](#) for BREYANZI or by scanning the QR code or see full PI provided by the BMS representative.

