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Breyanzi® **real-world evidence** in ~400 R/R LBCL patients from CIBMTR* registry

CIBMTR, Center for International Blood and Marrow Transplant Research.
*This analysis does not reflect the opinion of CIBMTR or its funding sources.

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.**

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(lisocabtagene maraleucel) SUSPENSION FOR IV INFUSION

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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 ≥ 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 ≥ 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 (≥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 ≥ 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 ≥ 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 (≥ 5%) included encephalopathy (20%), tremor (13%), aphasia (8%), headache (6%), dizziness (6%), and delirium (5%).

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Important Safety Information (continued)

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.

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

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.

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Important Safety Information (continued)

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 ≥ 30%) are fever, CRS, fatigue, musculoskeletal pain, and nausea.

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

Please see full Prescribing Information, including **Boxed WARNINGS** and Medication Guide.

References: 1. Breyanzi [package insert]. Summit, NJ: Bristol-Myers Squibb Company; 2023. **2.** Abramson JS, Palomba ML, Gordon LI, et al. Lisocabtagene maraleucel for patients with relapsed or refractory large B-cell lymphomas (TRANSCEND NHL 001): a multicentre seamless design study. *Lancet.* 2020;396(10254):839-852. **3.** Abramson J, Palomba M, Gordon L, et al. Two-year follow-up of TRANSCEND NHL 001, a multicenter phase 1 study of lisocabtagene maraleucel in relapsed or refractory large B-cell lymphomas. Presented at the 63rd American Society of Hematology Annual Meeting & Exposition; December 11-14, 2021; Atlanta, GA. **4.** Crombie J, Nastoupil LJ, Andreadis C, et al. Multicenter, real-world study in patients with R/R large B-cell lymphoma (LBCL) who received lisocabtagene maraleucel (liso-cel) in the United States (US). Presented at: the American Society of Hematology (ASH) Congress 2023; December 9-12, 2023; San Diego, California. Presentation 104. **5.** Lee DW, Santomasso BD, Locke FL, et al. ASTCT consensus grading for cytokine release syndrome and neurologic toxicity associated with immune effector cells. *Biol Blood Marrow Transplant.* 2019;25(4):625-638.

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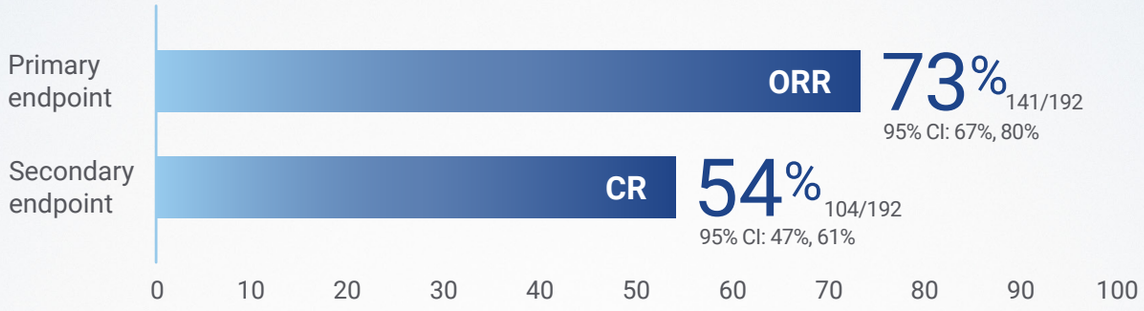
TRANSCEND 3L+ LBCL trial

Deep and durable complete response with a one-time* infusion[1†]

Response rates



Number of responders (n=141/192)

Median DOR: 16.7 months (95% CI: 5.3, NR)‡; range§: 0.0+ to 23.5+

Median DoCR: NR (95% CI: 16.7, NR)‡; range§: 0.7+ to 23.5+

Median DoPR: 1.4 months (95% CI: 1.1, 2.2)‡; range§: 0.0+ to 22.8+

An open-label, single-arm, multicenter, pivotal trial (N=269)[1]

Primary endpoint: ORR, safety[2]

Select secondary endpoints: CR, DOR, OS[2]

Patients were allowed to receive optional bridging therapy prior to receiving Breyanzi[1]

CI, confidence interval; CR, complete response; CRS, cytokine release syndrome; DoCR, duration of response if best response is CR; DoPR, duration of response if best response is partial response; DOR, duration of response; LBCL, large B-cell lymphoma; NR, not reached; NT, neurologic toxicity; ORR, overall response.

*Treatment process can take approximately 2 to 3 months and includes leukapheresis, manufacturing, administration, and adverse event monitoring. †Efficacy was established on the basis of CR rate and DOR, per the Lugano criteria, as assessed by an IRC. ‡Kaplan-Meier method was used to obtain 2-sided 95% confidence intervals. §A plus sign (+) indicates a censored value.

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In patients receiving BREYANZI after two or more lines of therapy for LBCL, CRS occurred in 46% (122/268), including ≥ 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 (≥10%) included fever (94%), hypotension (42%), tachycardia (28%), chills (23%), hypoxia (16%), and headache (12%).

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TRANSCEND 3L+ LBCL trial

Overall survival at 2-year follow-up[3]

Median OS was 27.3 months (95% CI: 16.2-45.6)[3]

- **51% of all patients were alive at 2 years**[3]
- Median (95% CI) follow-up, 29.3 months (26.2-30.4)[3]*

Analysis limitations:

OS was a secondary endpoint of TRANSCEND and was not statistically tested in the setting of a single-arm trial[3]

- OS data are not in the USPI and should be interpreted with caution in a single-arm trial. The statistical significance of OS is not known
- OS included survival data from patients who completed TRANSCEND and enrolled in the subsequent long-term follow-up study

Less than half of patients experienced Any Grade CRS/NT (n=268)[1]

CRS: 46% Any Grade, **4%** ≥ Grade 3
5 Median days to onset. Range: **1-15 days**
5 Median days of duration. Range: **1-17 days**

NT: 35% Any Grade; **12%** ≥ Grade 3
8 Median days to onset. Range: **1-46 days**
12 Median days of duration. Range: **1-87 days**

In the TRANSCEND trial, one patient had fatal CRS, and 2 had ongoing CRS at time of death. Three patients had fatal neurologic toxicity and 7 had ongoing neurologic toxicity at time of death.

*Reverse Kaplan-Meier method was used to calculate median (95% CI) of follow-up.

Important Safety Information

Cytokine Release Syndrome (continued): 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).

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R/R LBCL real-world evidence

Results in ~400 real-world R/R LBCL patients[4]

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Important information

- A noninterventional, observational study of 396 US patients enrolled in the CIBMTR Cellular Therapy Registry between February 2021 and November 2022 after infusion with Breyanzi® for R/R LBCL across 58 treatment sites
- Primary objective was to evaluate real-world clinical outcomes of Breyanzi, including ORR, CR, DOR, PFS, safety, and OS

SELECT DEMOGRAPHICS (N=396)

Age range

- 23-91; median age was 70

ECOG 0-1: 84%

ECOG ≥2: 7%

Lines of prior therapy

- Median (range): 3 (1-12)

Real-world study limitations

- Limitations of this study include its retrospective and observational design, limited follow-up, and heterogeneity in institutional standards for toxicity management across different centers
- Response assessment was per investigator discretion, and there was no independent review committee
- Results were analyzed and reported descriptively; no formal hypothesis testing was performed; analyses are not intended to be compared to controlled clinical trial data. Causality cannot be established based on real-world data. Therefore, outcomes should be interpreted with caution

ECOG, Eastern Cooperative Oncology Group; ORR, overall response rate; OS, overall survival; PFS, progression-free survival.

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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.

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R/R LBCL real-world evidence

Response rates with Breyanzi® in the real-world setting

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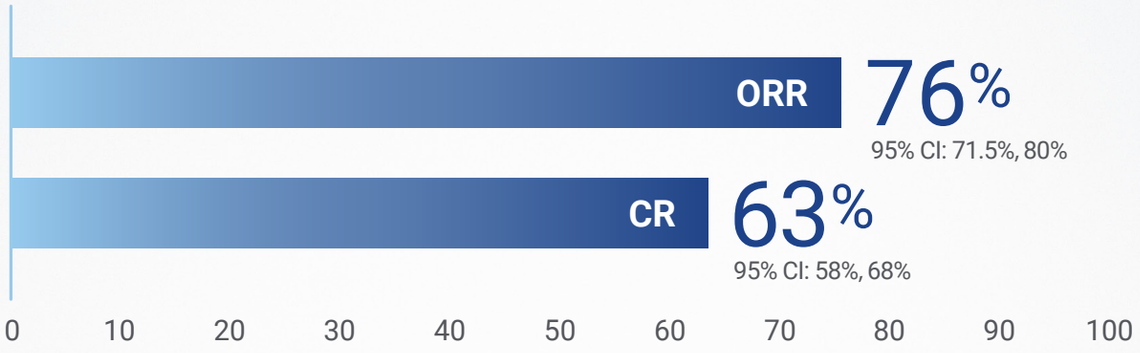
Consistent efficacy and safety results with Breyanzi across clinical trial and real-world settings[1,4]

Response rates (N=388)*



Median follow-up of 11.3 months

DOR (N=288)
Median DOR: NR (95% CI: NR, NR)
12-month DOR: 62% (95% CI: 53, 69)†

OS (N=396)
Median OS: NR (95% CI: NR, NR)†
12-month OS: 66% (95% CI: 60, 71)†

*Eligible for response assessment. †Based on Kaplan-Meier estimates.

Important Safety Information

Neurologic Toxicities (continued): In all patients combined receiving BREYANZI for LBCL, neurologic toxicities occurred in 33% (136/418), including ≥ 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 (≥ 5%) included encephalopathy (20%), tremor (13%), aphasia (8%), headache (6%), dizziness (6%), and delirium (5%).

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Consistent safety profile observed in real-world setting (N=396)[4]

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Cytokine release syndrome (CRS)*

51%
Any Grade CRS

3%
≥ Grade 3 CRS

Neurological events (NE)*

30%
Any Grade NE

11%
≥ Grade 3 NE

Grade 5 CRS or ICANS were observed in 3 and 3 patients, respectively, and all but 2 patients had concomitant causes of death, including disease progression (n=2). Grade 4 thrombocytopenia and/or persistent neutropenia at 30 days post-infusion was observed in 12% of patients.

ICANS; immune effector cell-associated neurotoxicity syndrome.
*American Society for Transplantation and Cellular Therapy (ASTCT) criteria were utilized for assessment of CRS and neurotoxicity in the real-world setting, while Lee et al, 2014 criteria for grading CRS and National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) for grading neurologic toxicities were utilized in TRANSCEND LBCL trial. There was a high concordance on the CRS grading per Lee and ASTCT criteria.[5]

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At the first sign of 1L treatment failure,* take the next step with Breyanzi®

- **Proven in a broad range of patients** with R/R LBCL across 2L and 3L studies
- **Real-world evidence** in ~400 R/R LBCL patients
- **Immediate slots available** to serve more eligible patients

Explore the breadth of clinical data at BreyanziHCP.com

***Lisocabtagene maraleucel is indicated for adult patients with LBCL R/R ≤12 months to first-line chemoimmunotherapy; or R/R after 1L chemoimmunotherapy and are not eligible for HSCT due to comorbidities or age.**

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Patients may enroll in support programs offered through Cell Therapy 360® after a certified CAR T cell therapy treatment center determines that Breyanzi is the right treatment for them. Visit us at **CellTherapy360.com** or call **1-888-805-4555** for more information.

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