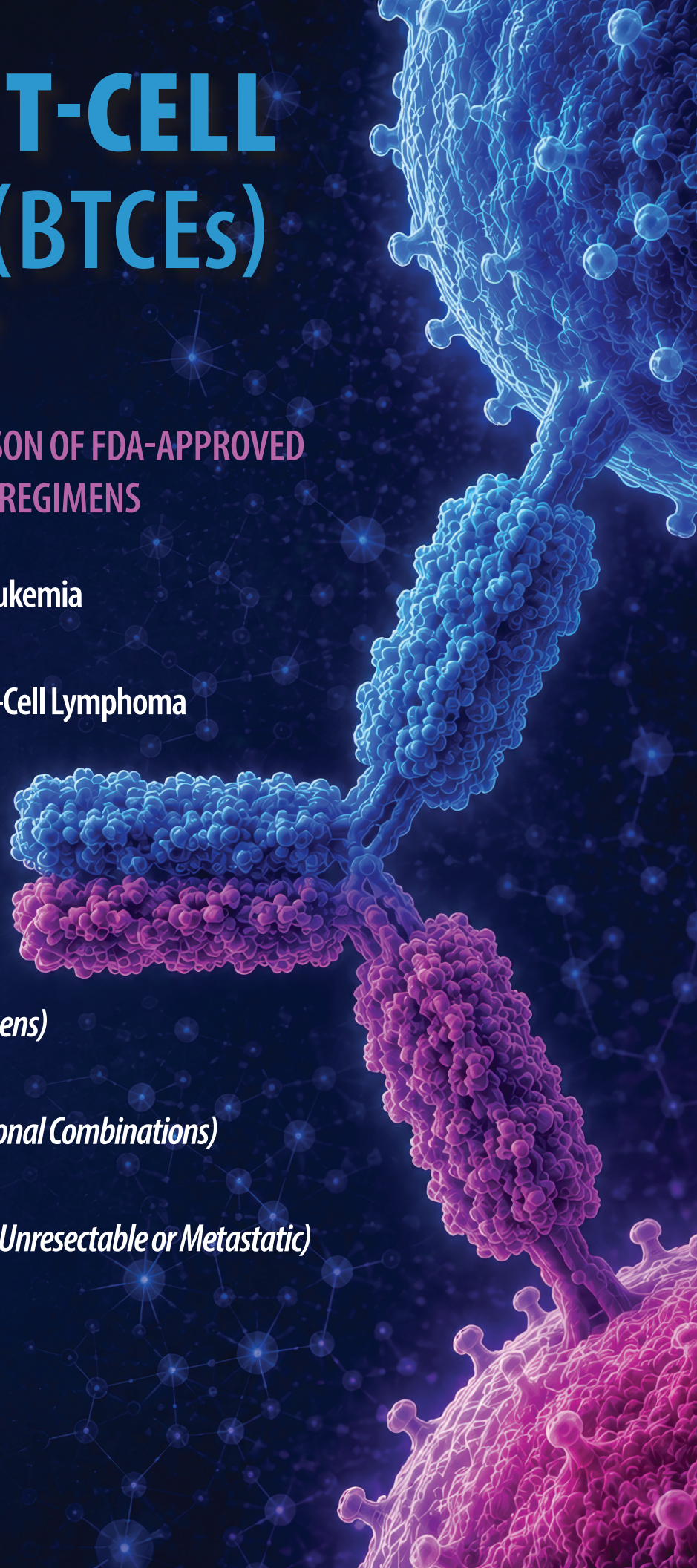
BISPECIFIC T-CELL ENGAGERS (BTCEs) DIRECTORY

DISEASE-STATE-SPECIFIC COMPARISON OF FDA-APPROVED AND OFF-LABEL/INVESTIGATIONAL REGIMENS



NCODA

TEAR-OUT TABLE FOR CLINICAL REFERENCE

TABLE 1: B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (AS OF JULY 2026)

CLINICAL ELEMENT	BLINATUMOMAB (BLINCYTO®) FDA-APPROVED
MANUFACTURER	Amgen Inc.
TARGET/ROUTE	CD19×CD3; continuous IV infusion
INDICATIONS/TRIALS	MRD-positive BCP-ALL (BLAST); R/R BCP-ALL (TOWER and pediatric studies); Philadelphia chromosome-negative BCP-ALL in consolidation (ECOG-ACRIN E1910 and pediatric consolidation studies)
SCHEDULE/SUD	Indication-, weight- and age-specific continuous-infusion schedules. Adult R/R induction C1: 9 mcg/day D1–7 then 28 mcg/day D8–28. MRD+ and consolidation typically use 28 mcg/day for 28 days in patients ≥45 kg. Consult PI for full cycle and pediatric dosing
PREMEDICATIONS	Intrathecal chemotherapy prophylaxis is recommended before and during treatment. Adults: MRD-positive disease – prednisone 100 mg IV or equivalent, such as dexamethasone 16 mg, one hour before the first dose of each cycle; R/R disease – dexamethasone 20 mg one hour before the first dose of each cycle, before the C1D8 SUD, and after an interruption ≥4 hours; consolidation – dexamethasone 20 mg IV within one hour before the first dose of each cycle. Pediatric patients: dexamethasone 5 mg/m^2 IV or orally, maximum 20 mg, as specified in the PI
HOSPITALIZATION/ OBSERVATION	MRD+ and consolidation: first three days of C1 and first 2 days of C2. R/R: first nine days of C1 and first 2 days of C2. For later cycle starts and reinitiation after interruption ≥4 hours, healthcare-professional supervision or hospitalization is recommended
CRS INCIDENCE BY INDICATION	MRD-positive 7% any grade; R/R 15% any grade and 3% Grade ≥3; consolidation 16% any grade and 4% Grade 3–4
CRS ONSET/PATTERN	Median onset two days after infusion start; indication-specific onset pattern not reported
CRS DURATION	Median time to resolution five days among resolved cases
NEUROLOGIC PROBLEMS: INCIDENCE	Overall neurologic toxicity approximately 65%; Grade≥3 approximately 13%. Signs/symptoms consistent with ICANS 7.5%
NEUROLOGIC PROBLEMS: ONSET/PATTERN	Median time to first neurologic event was within the first two weeks. ICANS-specific onset distribution not reported; may occur with CRS, after CRS or without CRS
NEUROLOGIC PROBLEMS: DURATION	Specific median duration not reported. PI states most neurologic toxicities resolved after interruption; some led to discontinuation
ANY GRADE AES/LABS ≥20%	MRD+: pyrexia 91%; infusion-related reactions 77%; infections, pathogen unspecified 39%; headache 39%; tremor 31%; chills 28% R/R adults, first cycle: pyrexia 55%; neutropenia 31%; infusion-related reactions 30%; infections, pathogen unspecified 28%; anemia 25%; headache 23%; thrombocytopenia 21% Adult consolidation: neutropenia 82%; thrombocytopenia 75%; anemia 59%; leukopenia 43%; headache 41%; infections, pathogen unspecified 35%; lymphopenia 32%; nausea 32%; diarrhea 29%; musculoskeletal pain 23%; tremor 23% Pediatric/young-adult consolidation: pyrexia 76%; nausea 43%; headache 37%; anemia 24%; hypogammaglobulinemia 24%; rash 22%. • Any grade laboratory abnormalities were not reported separately
GRADE ≥3 AES/LABS ≥10%	AEs – MRD+: neutropenia 15% R/R adults, first cycle: neutropenia 28%; anemia 19%; thrombocytopenia 18%; infection, pathogen unspecified 15% Adult consolidation: neutropenia 77%; thrombocytopenia 57%; leukopenia 41%; infection, pathogen unspecified 31%; lymphopenia 30%; anemia 29%; febrile neutropenia 19%; hypertension 10% Pediatric/young-adult consolidation: neutropenia 17%; anemia 15%; thrombocytopenia 15% Labs – R/R adults, first cycle: lymphocyte count decreased 80%; neutrophil count decreased 57%; white blood cell count decreased 53%; platelet count decreased 47%; hemoglobin decreased 29%; ALT increased 11% • MRD+ and consolidation laboratory abnormalities were not separately reported
REMS PROGRAM	No
INITIAL U.S. APPROVAL	2014

INTERPRETIVE CONVENTIONS

• Clinical adverse events and laboratory abnormalities are listed when the reported any grade incidence was ≥20% in the applicable source, with reported percentages retained. When a source table used a higher display threshold or did not report events or laboratory abnormalities down to 20%, unreported rates are not inferred.

• Rates should not be compared directly across regimens because populations, follow-up, grading methods, step-up schedules and safety-analysis sets differ.

• FFD = first full dose; SUD = step-up dose; observation language is abbreviated but preserves the operational requirements in the cited PI or study.

TABLE 2: DIFFUSE LARGE B-CELL LYMPHOMA /LARGE B-CELL LYMPHOMA (AS OF JULY 2026)

CLINICAL ELEMENT	EPCORITAMAB-BYSP (EPKINLY®) MONOTHERAPY FDA-APPROVED	GLOFITAMAB-GXBM (COLUMVI®) MONOTHERAPY FDA-APPROVED	EPCORITAMAB-BYSP (EPKINLY®) + GEMOX OFF-LABEL/INVESTIGATIONAL	GLOFITAMAB-GXBM (COLUMVI®) + GEMOX OFF-LABEL/INVESTIGATIONAL
MANUFACTURER	Genmab US, Inc. and AbbVie Inc.	Genentech, Inc.	Genmab US, Inc. and AbbVie Inc.	Genentech, Inc.
TARGET/ROUTE	CD20×CD3; SC	CD20×CD3; IV	CD20×CD3; SC + IV GemOx	CD20×CD3; IV + IV GemOx
POPULATION/TRIAL	R/R DLBCL NOS (including transformed indolent lymphoma) or HGBCL after ≥2 lines; EPCORE NHL-1	R/R DLBCL NOS or LBCL arising from FL after ≥2 lines; NP30179	R/R DLBCL after ≥1 line, ASCT-ineligible or prior ASCT failure; phase 1b/2 EPCORE NHL-2	R/R DLBCL after ≥1 line, transplant-ineligible; phase 3 STARGLO
SCHEDULE/SUD	28-day cycles. C1D1 0.16 mg, D8 0.8 mg, D15 48 mg FFD, D22 48 mg; C2–3 weekly; C4–9 q2wk; C10+ q4wk	Obinutuzumab 1,000 mg C1D1; glofitamab 2.5 mg C1D8, 10 mg C1D15, then 30 mg C2D1 and D1 q21d through C12	28-day cycles. Epcoritamab 0.16 mg D1, 0.8 mg D8, 48 mg FFD D15 and D22; C2-3 weekly; C4-9 q2wk; C10+ q4wk; GemOx D1 and D15 during C1-4	21-day cycles. Obinutuzumab C1D1; glofitamab 2.5 mg C1D8, 10 mg C1D15, then 30 mg C2–12 D1. GemOx D1 C1–8
PREMEDICATIONS	Acetaminophen 650–1,000 mg; diphenhydramine 50 mg/equivalent; dexamethasone 15 mg or prednisolone 100 mg/equivalent before each C1 dose and daily for three days after	Acetaminophen 500–1,000 mg; diphenhydramine 50 mg/equivalent; dexamethasone 20 mg/equivalent on C1D8, C1D15, C2D1, C3D1; continue if prior CRS	Prednisolone 100 mg/equivalent D1–4, D8–11, D15–18, D22–25 in C1; acetaminophen 650–1,000 mg and diphenhydramine 50 mg/equivalent on C1 dosing days	Dexamethasone 20 mg one hour before glofitamab until two 30-mg target doses received without CRS; regimen supportive care per study protocol
HOSPITALIZATION/ OBSERVATION	For C1D15 FFD, assess hospitalization versus outpatient monitoring based on comorbidities/situational factors; if outpatient, remain near a facility able to manage CRS	Hospitalize during and 24 hours after C1D8 2.5 mg. If any CRS with C1D8, hospitalize during and 24 hours after C1D15 10 mg. After prior G≥2 CRS, hospitalize during and 24 hours after next infusion	Trial required hospitalization for C1D15 FFD (and FFD in repriming cycles) and for 24 hours afterward	Trial required overnight hospitalization after the first glofitamab infusion (C1D8)
CRS INCIDENCE BY GRADE	51% overall: G1 37%, G2 17%, G3 2.5%; recurrent in 31%	70% overall: G1 52%, G2 14%, G3 2.8%, G4 1.4%; recurrent in 34%	52.4% overall: G1 28%, G2 23%, G3 1%; no G4–5 reported	44% overall: G1 31%, G2 11%, G3 2%; no G4–5 reported
CRS ONSET/PATTERN	92% in C1. By C1 dose: 6%, 12%, 43%, 5%. Median onset from most recent dose 24 hours (0–10 days); after FFD 21 hours (0–7 days)	By dose: 56% after 2.5 mg, 35% after 10 mg, 29% after initial 30 mg, 2.8% after later doses. Median onset after 2.5 mg: 14 hours (5–74)	84% of events in C1; 63% after FFD. Median onset not reported in primary article	Predominantly after initial 2.5-mg dose. Prior chart/source appendix: median onset approximately 14 hours after C1D8, 32 hours after C1D15, 38 hours after C2D1, and 37 hours after C3+ doses
CRS DURATION	Median 2 d (<1–27) across PI LBCL/FL populations; 98% resolved	Median 2 d (1–14); 98% resolved	All events resolved; median time to resolution not reported in primary article	All reported ICANS resolved with CRS resolution; median CRS duration not reported in primary article
NEUROLOGIC PROBLEMS: INCIDENCE	ICANS 6%: G1 4.5%, G2 1.3%, fatal 0.6%	Most frequent neurologic AEs: headache, peripheral neuropathy, dizziness/vertigo, mental-status changes; G≥3 neurologic AEs 2.1%. ICANS 4.8%	ICANS 2.9% (one each G1, G2, G3). Overall neurologic-toxicity incidence not reported	ICANS 2% (three G1–2 events and one G3 event). Grade ≥2 neurologic AEs 31% (broader category)
NEUROLOGIC PROBLEMS: ONSET/PATTERN	9/10 ICANS events in C1. Median onset 16.5 days (8–141) from treatment start and three days (1–13) after most recent dose	ICANS onset/pattern not reported	ICANS onset not reported	All ICANS occurred concurrently with CRS; regimen-specific onset not reported
NEUROLOGIC PROBLEMS: DURATION	Median ICANS duration four days (0–8); 90% resolved	ICANS and overall neurologic-toxicity duration not reported	All ICANS resolved; time to resolution not reported	All ICANS resolved with CRS resolution; duration not reported

ABBREVIATIONS: **AE**, adverse event; **ALL**, acute lymphoblastic leukemia; **ALT**, alanine aminotransferase; **ASCT**, autologous stem-cell transplant; **AST**, aspartate aminotransferase; **BCP**, B-cell precursor; **BCMA**, B-cell maturation antigen; **C**, cycle; **C1D1**, Cycle 1, Day 1; **CR**, complete response; **CRS**, cytokine release syndrome; **D**, day; **DLBCL**, diffuse large B-cell lymphoma; **DLL3**, delta-like ligand 3; **ES-SCLC**, extensive-stage small cell lung cancer; **FFD**, first full dose; **FL**, follicular lymphoma; **G**, grade; **GemOx**, gemcitabine and oxaliplatin; **GGT**, gamma-glutamyl transferase; **GPRC5D**, G protein-coupled receptor class C group 5 member D; **HGBCL**, high-grade B-cell lymphoma; **HLA**, human leukocyte antigen; **ICANS**, immune effector cell-associated neurotoxicity syndrome; **IMiD**, immunomodulatory drug; **IV**, intravenous; **LBCL**, large B-cell lymphoma; **MM**, multiple myeloma; **MRD**, measurable residual disease; **N/A**, not applicable; **NOS**, not otherwise specified; **PI**, proteasome inhibitor or prescribing information, as context indicates; **PR**, partial response; q2wk, every 2 weeks; q4wk, every 4 weeks; **R²**, rituximab plus lenalidomide; **R/R**, relapsed/refractory; **REMS**, Risk Evaluation and Mitigation Strategy; **RP2R**, recommended phase 2 regimen; **SC**, subcutaneous; **SD**, stable disease; **SUD**, step-up dose; **VGPR**, very good partial response; **WBC**, white blood cell count.

TABLE 2 *(CONTINUED)*: **DIFFUSE LARGE B-CELL LYMPHOMA /LARGE B-CELL LYMPHOMA** (AS OF JULY 2026)

CLINICAL ELEMENT	EPCORITAMAB-BYSP (EPKINLY®) MONOTHERAPY FDA-APPROVED	GLOFITAMAB-GXBM (COLUMVI®) MONOTHERAPY FDA-APPROVED	EPCORITAMAB-BYSP (EPKINLY®) + GEMOX OFF-LABEL/INVESTIGATIONAL	GLOFITAMAB-GXBM (COLUMVI®) + GEMOX OFF-LABEL/INVESTIGATIONAL
ANY GRADE AES/LABS ≥20%	AEs – CRS 51%; fatigue 29%; musculoskeletal pain 28%; injection-site reactions 27%; pyrexia 24%; abdominal pain 23%; diarrhea 20%; nausea 20% Labs – lymphocyte count decreased 87%; hemoglobin decreased 62%; sodium decreased 56%; phosphate decreased 56%; white blood cell count decreased 53%; neutrophil count decreased 50%; platelet count decreased 48%; AST increased 48%; ALT increased 45%; potassium decreased 34%; magnesium decreased 31%; creatinine increased 24%; potassium increased 21%	AEs – CRS 70%; musculoskeletal pain 21%; fatigue 20%; rash 20% Labs – lymphocyte count decreased 90%; fibrinogen decreased 84%; hemoglobin decreased 72%; phosphate decreased 69%; neutrophil count decreased 56%; platelet count decreased 56%; sodium decreased 49%; calcium decreased 48%; GGT increased 33%; potassium decreased 32%; uric acid increased 23%	AEs – infections 71.8%; anemia 59.2%; CRS 52.4%; diarrhea 46.6%; nausea 39.8%; fatigue 35.0%; COVID-19 29.1%; pyrexia 29.1%; peripheral neuropathy 25.2%; cough 20.4% Labs – thrombocytopenia 72.8%; neutropenia 65.0%; hypokalemia 31.1%; ALT increased 28.2%; AST increased 25.2%	AEs – CRS 44%; anemia 41%; nausea 39%; peripheral neuropathy 36%; diarrhea 34% Labs – thrombocytopenia 48%; neutropenia 42%; AST increased 33%; ALT increased 32%
GRADE ≥3 AES/LABS ≥10%	AEs – none met the threshold Labs – lymphocyte count decreased 77%; neutrophil count decreased 32%; white blood cell count decreased 22%; hemoglobin decreased 12%; platelet count decreased 12%	AEs – none met the threshold Labs – lymphocyte count decreased 83%; phosphate decreased 28%; neutrophil count decreased 26%; uric acid increased 23%; fibrinogen decreased 21%	AEs – anemia 42.7%; infections 29.1%; COVID-19 10.7% Labs – thrombocytopenia 59.2%; neutropenia 57.3%	AEs – individual AEs not reported. 78% experienced at least one Grade ≥3 AE Labs – neutropenia 34%
REMS PROGRAM	No	No	No	No
INITIAL U.S. APPROVAL	2023	2023	N/A – combination is not FDA-approved	N/A – combination is not FDA-approved

TABLE 3: **EXTENSIVE-STAGE SMALL CELL LUNG CANCER** (AS OF JULY 28, 2026)

CLINICAL ELEMENT	TARLATAMAB-DLLE (IMDELLTRA®) FDA-APPROVED
MANUFACTURER	Amgen Inc.
TARGET/ROUTE	DLL3×CD3; IV
INDICATION/TRIALS	ES-SCLC with progression on or after platinum-based chemotherapy; DeLLphi-301 and phase 3 DeLLphi-304
SCHEDULE/SUD	1 mg C1D1; 10 mg C1D8 FFD; 10 mg C1D15; then 10 mg D1 and D15 every 28 days
PREMEDICATIONS	C1D1 and C1D8: dexamethasone 8 mg IV or equivalent within one hour before tarlatamab; administer 1 L normal saline IV over two to four hours immediately after the infusion. Ensure adequate hydration before each dose
HOSPITALIZATION/OBSERVATION	C1D1 and C1D8: monitor from infusion start for 22–24 hours in appropriate healthcare setting; remain within one hour of an appropriate facility for a total of 48 hours with caregiver. C1D15 and C2 doses: observe six to eight hours post-infusion. C3–4: three to four hours. C5+: two hours. Extend after prior G≥2 CRS/ICANS/neurologic toxicity per PI
CRS INCIDENCE BY GRADE	Pooled: 57% overall: G1 39%, G2 15%, G3 1.7%, G4 0.2%; recurrent in 24%
CRS ONSET/PATTERN	Among affected patients: 73% had CRS after first dose, 60% after second, 15% after third/later. Median onset: all-grade 16 h (infusion start–15 days); G≥2 15 h (infusion start–15 days)
CRS DURATION	Median duration not reported in current PI pooled warning
NEUROLOGIC PROBLEMS: INCIDENCE	Overall neurologic toxicity 65% (G≥3 7%; fatal 0.2%). Signs/symptoms consistent with ICANS 10%; ICANS 4.7%; recurrent ICANS 1.5%; one fatal ICANS
NEUROLOGIC PROBLEMS: ONSET/PATTERN	Most ICANS after C1D1 or C1D8; can occur weeks later. Median onset from first dose 16 d (1–862)
NEUROLOGIC PROBLEMS: DURATION	Median time to ICANS resolution 4 d (1–40). Overall neurologic-toxicity duration not reported
ANY GRADE AES/LABS ≥20%	Pooled AEs – CRS 57%; fatigue 48%; decreased appetite 38%; dysgeusia 34%; pyrexia 33%; constipation 31%; musculoskeletal pain 31%; nausea 25% DeLLphi-304 labs – lymphocyte count decreased 65%; sodium decreased 57%; hemoglobin decreased 51%; white blood cell count decreased 50%; potassium decreased 41%; AST increased 40%; sodium increased 35%; ALT increased 32%; activated partial thromboplastin time increased 26%; platelet count decreased 25%; creatinine increased 23%; alkaline phosphatase increased 22%; magnesium decreased 21%; potassium increased 21%; creatine phosphokinase increased 21%
GRADE ≥3 AES/LABS ≥10%	AEs – DeLLphi-300/301: fatigue 10%. No DeLLphi-304 adverse event met the threshold Labs – DeLLphi-300/301: lymphocyte count decreased 57%; sodium decreased 16%. DeLLphi-304: lymphocyte count decreased 27%; neutrophil count decreased 10%
REMS PROGRAM	No
INITIAL U.S. APPROVAL	2024

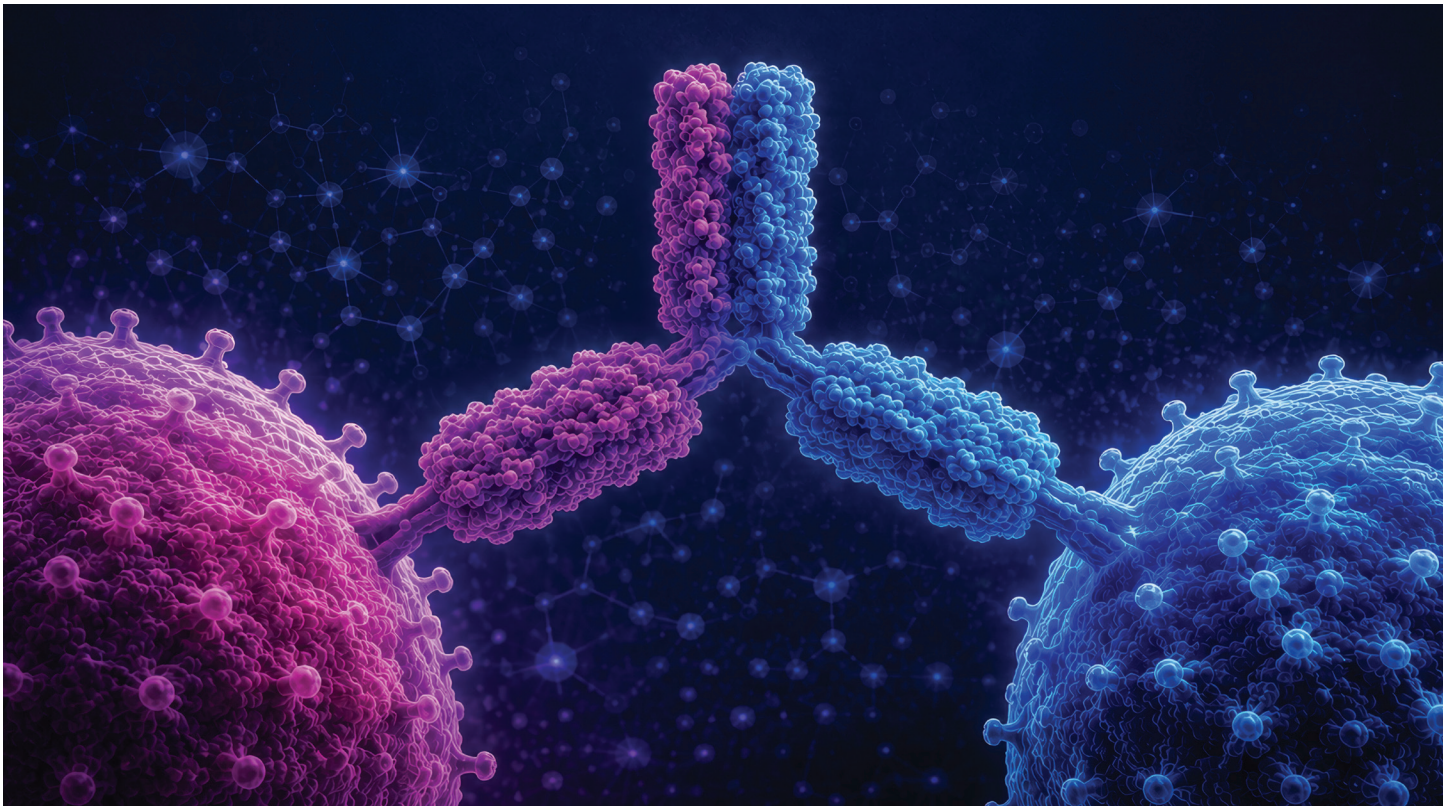
TEAR-OUT TABLE FOR CLINICAL REFERENCE

TABLE 4: FOLLICULAR LYMPHOMA (AS OF JULY 2026)

CLINICAL ELEMENT	MOSUNETUZUMAB-AXGB (LUNSUMIO®) IV FDA-APPROVED	MOSUNETUZUMAB-AXGB (LUNSUMIO VELO™) SC FDA-APPROVED	EPCORITAMAB-BYSP (EPKINLY®) MONOTHERAPY FDA-APPROVED	EPCORITAMAB-BYSP (EPKINLY®) + LENALIDOMIDE + RITUXIMAB (R^2) FDA-APPROVED
MANUFACTURER	Genentech, Inc.	Genentech, Inc.	Genmab US, Inc. and AbbVie Inc.	Genmab US, Inc. and AbbVie Inc.
TARGET/ROUTE	CD20×CD3; IV	CD20×CD3; SC	CD20×CD3; SC	CD20×CD3; SC epcoritamab + oral lenalidomide + IV rituximab
INDICATION/TRIAL	R/R FL after ≥2 lines; GO29781	R/R FL after ≥2 lines; GO29781 SC cohort	R/R FL after ≥2 lines; EPCORE NHL-1	R/R FL; studied after ≥1 line; EPCORE FL-1
SCHEDULE/SUD	21-day cycles. C1D1 1 mg, D8 2 mg, D15 60 mg FFD; C2D1 60 mg; C3+ D1 30 mg. Up to eight cycles for CR; up to 17 for PR/SD	21-day cycles. C1D1 5 mg; C1D8 45 mg FFD; C1D15 45 mg; C2+ D1 45 mg. Up to 8 cycles for CR; up to 17 for PR/SD	28-day cycles. C1: 0.16 mg D1, 0.8 mg D8, 3 mg D15, 48 mg FFD D22; C2–3 D1/8/15/22; C4–9 D1/15; C10+ D1	28-day cycles. Same C1 SUD. Epcoritamab C1–3 D1/8/15/22, C4–12 D1; lenalidomide D1–21 C1–12; rituximab C1 D1/8/15/22 and C2–5 D1
PREMEDICATIONS	Acetaminophen 500–1,000 mg; diphenhydramine 50–100 mg/equivalent; dexamethasone 20 mg or methylprednisolone 80 mg. Give C1–2 and after prior CRS	Acetaminophen 500–1,000 mg; diphenhydramine 50–100 mg/equivalent; dexamethasone 20 mg or methylprednisolone 80 mg. Give C1 and after prior CRS	Acetaminophen 650–1,000 mg; diphenhydramine 50 mg/equivalent; dexamethasone 15 mg or prednisolone 100 mg/equivalent before each C1 dose and daily for 3 days after; continue after prior G2–3 CRS	Same epcoritamab C1 pre/post-medications; follow component labeling for additional supportive care
HOSPITALIZATION/OBSERVATION	No routine admission mandated. At first CRS sign, evaluate for hospitalization. After resolved G2 CRS, monitor more frequently and consider hospitalization for next dose; follow PI for higher grades/restarts	No routine admission mandated. At first CRS sign, evaluate for hospitalization. After resolved G2 CRS, monitor more frequently and consider hospitalization; after resolved G3, hospitalize for next dose	For first 48-mg dose (C1D22), assess whether hospitalization or outpatient monitoring is appropriate based on comorbidities/situational factors. If outpatient, remain near a facility able to manage CRS	Same individualized inpatient-versus-outpatient assessment for C1D22 FFD; remain near capable facility if outpatient
CRS INCIDENCE BY GRADE	39% overall: G1 28%, G2 15%, G3 2%, G4 0.5%; recurrent in 28% of affected patients	30% overall: G1 20%, G2 7%, G3 2.1%; recurrent in 14% of affected patients	49% overall: G1 45%, G2 9%, no G≥3 reported with recommended three-step schedule; recurrent in 48%	24% overall: G1 19%, G2 5%, no G≥3 reported with recommended schedule; serious CRS reactions 12%; recurrent in 41%
CRS ONSET/PATTERN	By dose: C1D1 15%, C1D8 5%, C1D15 33%, C2D1 5%, later 1%. Median onset: five hours (one hour to three days), 28 hours (five hours to three days), 25 hours (0.1 hours to 16 days), and 46 hours (12 hours to three days), respectively	By dose: C1D1 19%, C1D8 13%, C1D15 2.1%. Median onset: 17 hours (7–33) after C1D1 and 62 hours (30–113) after C1D8	88% of CRS occurred in C1. By C1 dose: 12%, 6%, 15%, and 37%. Median onset from most recent dose 59 hours (0.1 to seven days); after FFD 61 hours (0.1 to seven days)	88% occurred in C1. By C1 dose: 5%, 3.8%, 2.3%, and 18%. Median onset from most recent dose 78 hours (0.2–12 days); after FFD 41 hours (0.3–12 days)
CRS DURATION	Median three days (1–29)	Median two days (1–15); all resolved	Across LBCL/FL PI populations: median two days (<1–27); 98% resolved	Across LBCL/FL PI populations: median two days (<1–27); 98% resolved
NEUROLOGIC PROBLEMS: INCIDENCE	Overall neurologic toxicity 39%; G3 3%. ICANS 1% (G1 0.5%, G2 0.5%). Broader LUNSUMIO/VELO pool: ICANS/suspected ICANS 2.2% (20 G1–2; 1 G3)	Overall neurologic toxicity 53%; G3 1.1%. ICANS/suspected ICANS 3.1% (all G1). Broader pooled ICANS/suspected ICANS 2.2%	ICANS 6% (G1 3.9%, G2 2.4%) in PI safety set; broader neurologic-toxicity incidence not reported	ICANS 0.8% (1/131; G1); broader neurologic-toxicity incidence not reported
NEUROLOGIC PROBLEMS: ONSET/PATTERN	Pooled ICANS: 75% in C1; median onset 17 days (1–48) from treatment course context	Pooled ICANS: 75% in C1; median onset 17 days (1–48)	Median ICANS onset 22 days (14–66) from treatment start and three days (0.4–7) after most recent dose	ICANS onset not reported (single event)
NEUROLOGIC PROBLEMS: DURATION	Pooled ICANS: 88% resolved; median three days (1–20). Overall neurologic-toxicity duration not reported	Pooled ICANS: 88% resolved; median three days (1–20). Overall neurologic-toxicity duration not reported	Median ICANS duration two days (1–7); 100% resolved	Not reported

TABLE 4 *(CONTINUED)*: **FOLLICULAR LYMPHOMA** (AS OF JULY 2026)

CLINICAL ELEMENT	MOSUNETUZUMAB-AXGB (LUNSUMIO®) IV FDA-APPROVED	MOSUNETUZUMAB-AXGB (LUNSUMIO VELO™) SC FDA-APPROVED	EPCORITAMAB-BYSP (EPKINLY®) MONOTHERAPY FDA-APPROVED	EPCORITAMAB-BYSP (EPKINLY®) + LENALIDOMIDE + RITUXIMAB (R^2) FDA-APPROVED
ANY GRADE AES/LABS ≥20%	AEs – CRS 44%; fatigue 42%; rash 39%; headache 32%; pyrexia 29%; musculoskeletal pain 28%; cough 22%; pruritus 21%; peripheral neuropathy 20% Labs – lymphocyte count decreased 100%; phosphate decreased 78%; hemoglobin decreased 68%; neutrophil count decreased 58%; platelet count decreased 46%; glucose increased 42%; AST increased 39%; GGT increased 34%; magnesium decreased 34%; potassium decreased 33%; ALT increased 32%; uric acid increased 22%	AEs – injection-site reactions 69%; fatigue 39%; rash 35%; CRS 30%; COVID-19 27%; musculoskeletal pain 20%; diarrhea 20% Labs – lymphocyte count decreased 84%; hemoglobin decreased 60%; neutrophil count decreased 50%; phosphate decreased 48%; platelet count decreased 33%; ALT increased 34%; GGT increased 31%; uric acid increased 28%; AST increased 28%; potassium decreased 27%; magnesium decreased 25%	AEs – injection-site reactions 58%; CRS 49%; COVID-19 40%; fatigue 37%; upper respiratory tract infection 29%; musculoskeletal pain 28%; rash 28%; diarrhea 26%; pyrexia 26%; cough 20%; headache 20% Labs – lymphocyte count decreased 94%; hemoglobin decreased 59%; white blood cell count decreased 58%; neutrophil count decreased 55%; sodium decreased 51%; platelet count decreased 49%; ALT increased 47%; AST increased 44%; creatinine increased 36%; alkaline phosphatase increased 29%; bilirubin increased 28%; potassium decreased 20%; magnesium decreased 20%	AEs – rash 46%; upper respiratory tract infection 33%; fatigue 31%; injection-site reactions 27%; constipation 26%; diarrhea 26%; CRS 24%; pneumonia 24%; COVID-19 23%; fever 23% Labs – neutrophil count decreased 86%; lymphocyte count decreased 86%; hemoglobin decreased 66%; ALT increased 58%; platelet count decreased 50%; phosphate decreased 49%; sodium decreased 43%; potassium decreased 41%; AST increased 40%
GRADE ≥3 AES/LABS ≥10%	AEs – none met the threshold Labs – lymphocyte count decreased 98%; phosphate decreased 46%; glucose increased 42%; neutrophil count decreased 40%; uric acid increased 22%; hemoglobin decreased 12%; platelet count decreased 10%	AEs – none met the threshold Labs – lymphocyte count decreased 69%; uric acid increased 28%; neutrophil count decreased 26%; phosphate decreased 11%; hemoglobin decreased 10%	AEs – COVID-19 19%; pneumonia 13% Labs – lymphocyte count decreased 82%; neutrophil count decreased 30%; white blood cell count decreased 19%; hemoglobin decreased 10%	AEs – pneumonia 16%; rash 11% Labs – neutrophil count decreased 67%; lymphocyte count decreased 62%; platelet count decreased 10%
REMS PROGRAM	No	No	No	No for EPKINLY; Yes for lenalidomide under the lenalidomide REMS
INITIAL U.S. APPROVAL	2022	2025	2023	2025



TEAR-OUT TABLE FOR CLINICAL REFERENCE

TABLE 5: MULTIPLE MYELOMA — FDA-APPROVED REGIMENS (AS OF JULY 2026)

CLINICAL ELEMENT	TECLISTAMAB-CQYV (TECVAYLI®) MONOTHERAPY	TECLISTAMAB-CQYV (TECVAYLI®) + DARATUMUMAB/HYALURONIDASE (DARZALEX FASPRO®)	TALQUETAMAB-TGVS (TALVEY®) MONOTHERAPY
MANUFACTURER	Janssen Biotech, Inc.	Janssen Biotech, Inc.	Janssen Biotech, Inc.
TARGET/ROUTE	BCMA×CD3; SC	BCMA×CD3; SC + SC anti-CD38	GPRC5D×CD3; SC
INDICATION/TRIAL	R/R MM after ≥4 lines including PI, IMiD, anti-CD38; MajesTEC-1	R/R MM after ≥1 prior line including PI and IMiD; phase 3 MajesTEC-3	R/R MM after ≥4 lines including PI, IMiD, anti-CD38; MonumenTAL-1
SCHEDULE/SUD	0.06 mg/kg SUD1, 0.3 mg/kg SUD2, 1.5 mg/kg FFD; then weekly. May reduce to q2wk after CR+ maintained ≥6 months	Daratumumab/hyaluronidase Day 0. Teclistamab 0.06 mg/kg D1, 0.3 mg/kg D3, 1.5 mg/kg FFD D7; 1.5 mg/kg weekly weeks 2–8; 3 mg/kg q2wk weeks 9–24; 3 mg/kg q4wk weeks 25+	Weekly: 0.01 mg/kg, 0.06 mg/kg, then 0.4 mg/kg FFD and weekly. q2wk: 0.01 mg/kg, 0.06 mg/kg, 0.4 mg/kg, then 0.8 mg/kg FFD and q2wk
PREMEDICATIONS	Acetaminophen 650–1,000 mg; diphenhydramine 50 mg/equivalent; dexamethasone 16 mg before SUD1, SUD2, and FFD	Same teclistamab premedications one to three hours before each SUD and FFD	Acetaminophen 650–1,000 mg; diphenhydramine 50 mg/equivalent; dexamethasone 16 mg/equivalent before each SUD and FFD
HOSPITALIZATION/OBSERVATION	Hospitalize 48 hours after SUD1 and SUD2. Remain near a healthcare facility and monitor daily for 48 hours after FFD	Same current TECVAYLI PI requirement: 48-hour hospitalization after SUD1 and SUD2; proximity to facility and daily monitoring for 48 hours after FFD	Hospitalize 48 hours after every dose in the step-up schedule, including the first treatment dose
CRS INCIDENCE BY GRADE	MajesTEC-1: 72% overall: G1 50%, G2 21%, G3 0.6%; no G4–5 reported	MajesTEC-3: 60% overall; G3–4 0% (therefore events were G1–2). Current PI pooled monotherapy/combination: 64% (G1 46%, G2 18%, G3 0.2%)	76% overall: G1 57%, G2 17%, G3 1.5%; recurrent in 30%
CRS ONSET/PATTERN	Current PI pooled: SUD1 37%, SUD2 32%, FFD 20%; first onset after later doses 2.5%. Median onset 2 d (1–9) after most recent dose	Current PI pooled: SUD1 37%, SUD2 32%, FFD 20%; first onset after later doses 2.5%. Median onset two days (1–9)	Most after SUD1 (29%) or SUD2 (44%); 33% after SUD3 in q2wk schedule; 30% after first 0.4 mg/kg and 12% after first 0.8 mg/kg. Median onset 27 hours (0.1–167)
CRS DURATION	Current PI pooled median two days (1–22)	Current PI pooled median two days (1–22)	Median 17 hours (0–622)
NEUROLOGIC PROBLEMS: INCIDENCE	Current PI pooled overall neurologic toxicity 60% (G3–4 6%; fatal 0.4%). MajesTEC-1 ICANS 6%; recurrent 1.8%	Current PI pooled overall neurologic toxicity 60% (G3–4 6%; fatal 0.4%). MajesTEC-3 ICANS 1.1%, including one G4 event	Overall neurologic toxicity including ICANS 55% (G3–4 6%). ICANS 9%; recurrent 3%
NEUROLOGIC PROBLEMS: ONSET/PATTERN	ICANS most often after SUD1 (1.2%), SUD2 (0.6%), or FFD (1.8%); <3% first occurred after later doses. Median onset four days (2–8) after most recent dose	All ICANS occurred during SUD. Median onset two days (1–3) after most recent dose	ICANS clustered during SUD/FFD. Median onset 2.5 days (1–16) after most recent dose
NEUROLOGIC PROBLEMS: DURATION	Median ICANS duration three days (1–20). Overall neurologic-toxicity duration not reported	Median ICANS duration two days (1–2). Overall neurologic-toxicity duration not reported	Median ICANS duration two days (1–22). Overall neurologic-toxicity duration not reported
ANY GRADE AES/LABS ≥20%	AEs — pyrexia 76%; CRS 72%; musculoskeletal pain 44%; injection-site reactions 37%; fatigue 33%; upper respiratory tract infection 26%; nausea 25%; headache 25%; pneumonia 24%; diarrhea 21% Labs — lymphocyte count decreased 92%; white blood cell count decreased 86%; neutrophil count decreased 84%; platelet count decreased 71%; albumin decreased 68%; hemoglobin decreased 67%; alkaline phosphatase increased 42%; phosphorus decreased 38%; GGT increased 37%; sodium decreased 35%; AST increased 34%; calcium decreased 31%; creatinine increased 30%	AEs — hypogammaglobulinemia 84%; upper respiratory tract infection 79%; CRS 60%; cough 53%; diarrhea 52%; musculoskeletal pain 50%; COVID-19 45%; pneumonia 42%; injection-site reactions 41%; fatigue 39%; pyrexia 37%; headache 26%; nausea 23%; gastroenteritis 20%; weight decreased 20% Labs — lymphocyte count decreased 99%; white blood cell count decreased 94%; neutrophil count decreased 91%; platelet count decreased 73%; hemoglobin decreased 64%; ALT increased 60%; AST increased 55%; potassium decreased 52%; GGT increased 51%; lipase increased 49%; sodium decreased 46%; amylase increased 31%	AEs — pyrexia 83%; CRS 76%; dysgeusia 70%; nail disorder 50%; musculoskeletal pain 43%; skin disorder 41%; rash 38%; fatigue 37%; weight decreased 35%; dry mouth 34%; xerosis 30%; dysphagia 23%; upper respiratory tract infection 22%; diarrhea 21%; hypotension 21%; headache 21% Labs — lymphocyte count decreased 90%; white blood cell count decreased 73%; hemoglobin decreased 67%; albumin decreased 66%; neutrophil count decreased 64%; platelet count decreased 62%; alkaline phosphatase increased 49%; phosphate decreased 44%; GGT increased 38%; ALT increased 33%; potassium decreased 31%; sodium decreased 31%; AST increased 31%
GRADE ≥3 AES/LABS ≥10%	AEs — pneumonia 15% Labs — lymphocyte count decreased 84%; neutrophil count decreased 56%; white blood cell count decreased 41%; hemoglobin decreased 33%; platelet count decreased 22%; phosphorus decreased 13%; sodium decreased 10%	AEs — pneumonia 33%; upper respiratory tract infection 17% Labs — lymphocyte count decreased 95%; neutrophil count decreased 78%; white blood cell count decreased 60%; platelet count decreased 21%; lipase increased 18%; hemoglobin decreased 17%; potassium decreased 15%; sodium decreased 10%	AEs — none met the threshold Labs — lymphocyte count decreased 80%; white blood cell count decreased 35%; neutrophil count decreased 35%; hemoglobin decreased 30%; platelet count decreased 22%; phosphate decreased 13%
REMS PROGRAM	Yes — TECVAYLI and TALVEY REMS	Yes — TECVAYLI and TALVEY REMS	Yes — TECVAYLI and TALVEY REMS
INITIAL U.S. APPROVAL	2022	2026	2023

TABLE 5 *(CONTINUED)*: **MULTIPLE MYELOMA — FDA-APPROVED REGIMENS** (AS OF JULY 2026)

CLINICAL ELEMENT	ELRANATAMAB-BCMM (ELREXFIO®)	LINVOSELTAMAB-GCPT (LYNOZYFIC™)
MANUFACTURER	Pfizer Inc.	Regeneron Pharmaceuticals, Inc.
TARGET/ROUTE	BCMA×CD3; SC	BCMA×CD3; IV
INDICATION/TRIAL	R/R MM after ≥4 lines including PI, IMiD, anti-CD38; MagnetisMM-3	R/R MM after ≥4 lines including PI, IMiD, anti-CD38; LINKER-MM1
SCHEDULE/SUD	12 mg D1, 32 mg D4, 76 mg FFD D8; weekly through week 24; response-adapted q2wk weeks 25–48 and q4wk week 49+	5 mg D1, 25 mg D8, 200 mg FFD D15; weekly through week 13, q2wk thereafter; q4wk after week 24 if VGPR+ maintained and ≥17 full doses
PREMEDICATIONS	Acetaminophen 650 mg; diphenhydramine 25 mg; dexamethasone 20 mg/equivalent before each SUD and FFD	Acetaminophen 650–1,000 mg; diphenhydramine 25 mg; dexamethasone 40 mg before SUD1, SUD2, and first full dose; then 10 mg as tolerated; may discontinue after tolerated dose per PI
HOSPITALIZATION/OBSERVATION	Hospitalize 48 hours after SUD1 and 24 hours after SUD2	Hospitalize 24 hours after SUD1 and 24 h after SUD2. No routine admission after FFD specified
CRS INCIDENCE BY GRADE	58% overall: G1 44%, G2 14%, G3 0.5%; recurrent in 13%	46% overall: G1 35%, G2 10%, G3 0.9%; recurrent in 20%
CRS ONSET/PATTERN	SUD1 43%, SUD2 19%, FFD 7%, later dose 1.6%. Median onset two days (1–9)	SUD1 38%; SUD2 17%; first full dose 10%; second full dose 3.6%. Median onset 11 hours (−1 to 184) from end of infusion
CRS DURATION	Median two days (1–19)	Median 15 hours (1–76)
NEUROLOGIC PROBLEMS: INCIDENCE	Overall neurologic toxicity 59% (G3–4 7%). ICANS 3.3%; recurrent 1.1%	Overall neurologic toxicity 54% (G3–4 8%). ICANS 8% (G3 2.6%); recurrent in one patient
NEUROLOGIC PROBLEMS: ONSET/PATTERN	ICANS: SUD1 2.7%; SUD2 0.5%; later doses 0.5%. Median onset three days (1–4) after most recent dose	ICANS: 5% after SUD1; 1.8% first after SUD2; one first after later full dose. Median onset one day (1–4) after most recent dose
NEUROLOGIC PROBLEMS: DURATION	Median ICANS duration two days (1–18). Overall neurologic-toxicity duration not reported	Median ICANS duration two days (1–11). Overall neurologic-toxicity duration not reported
ANY GRADE AES/LABS ≥20%	AEs — CRS 58%; fatigue 43%; injection-site reactions 37%; diarrhea 36%; upper respiratory tract infection 36%; musculoskeletal pain 34%; pneumonia 32%; decreased appetite 26%; rash 26%; cough 24%; pyrexia 21%; nausea 21% Labs — lymphocyte count decreased 91%; white blood cell count decreased 69%; hemoglobin decreased 68%; neutrophil count decreased 62%; platelet count decreased 61%; albumin decreased 55%; AST increased 40%; creatinine increased 38%; potassium decreased 36%; ALT increased 36%; alkaline phosphatase increased 34%; creatinine clearance decreased 32%	AEs — musculoskeletal pain 53%; CRS 46%; cough 39%; upper respiratory tract infection 35%; diarrhea 35%; fatigue 34%; pneumonia 28%; nausea 23%; headache 22%; dyspnea 21% Labs — lymphocyte count decreased 97%; hemoglobin decreased 72%; platelet count decreased 64%; white blood cell count decreased 63%; neutrophil count decreased 62%; AST increased 61%; phosphorus decreased 55%; creatinine increased 47%; ALT increased 46%
GRADE ≥3 AES/LABS ≥10%	AEs — pneumonia 19%; sepsis 11% Labs — lymphocyte count decreased 84%; neutrophil count decreased 51%; hemoglobin decreased 43%; white blood cell count decreased 40%; platelet count decreased 32%; creatinine clearance decreased 10%	AEs — pneumonia 21% Labs — lymphocyte count decreased 92%; neutrophil count decreased 47%; hemoglobin decreased 42%; white blood cell count decreased 31%; phosphorus decreased 24%; platelet count decreased 19%; AST increased 10%
REMS PROGRAM	Yes — ELREXFIO REMS	Yes — LYNOZYFIC REMS
INITIAL U.S. APPROVAL	2023	2025

IMPORTANT NOTICE

NCODA has developed this bispecific T-cell engager resource. This resource is intended as an educational aid, does not provide individual medical advice, and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with the medications. The materials contained in this platform do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA. NCODA does not ensure the accuracy of the information presented and assumes no liability relating to its accuracy. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare provider. It is the individual's sole responsibility to seek guidance from a qualified healthcare professional.

Kelly Brunk

Madelyn Floysand

Chart updated by **Kelly Brunk**, PharmD, MBA, BCOP, Senior Manager of Clinical Excellence at NCODA, Yorkville, Illinois, and **Madelyn Floysand,** PharmD, Associate Manager of Clinical Excellence at NCODA, Denver.

TABLE 6: MULTIPLE MYELOMA — OFF-LABEL/INVESTIGATIONAL COMBINATIONS (AS OF JULY 2026)

CLINICAL ELEMENT	TALQUETAMAB-TGVS (TALVEY®) + TECLISTAMAB-CQYV (TECVAYLI®)	TALQUETAMAB-TGVS (TALVEY®) + DARATUMUMAB/HYALURONIDASE (DARZALEX FASPRO®)	TALVEY® + DARZALEX FASPRO® + POMALIDOMIDE (POMALYST®)
MANUFACTURER	Janssen Biotech, Inc.	Janssen Biotech, Inc.	Janssen Biotech, Inc.; branded pomalidomide: Bristol Myers Squibb
TRIAL/POPULATION	Phase 1b/2 RedirecTT-1; heavily pretreated R/R MM; RP2R n=44	Phase 3 MonumenTAL-3; R/R MM after ≥1 line; n=287 randomized	Phase 3 MonumenTAL-3; R/R MM after ≥1 line; n=287 randomized
REGIMEN	RP2R: talquetamab 0.8 mg/kg + teclistamab 3 mg/kg q2wk after study SUD; agents given same day, approximately 30 min apart	Talquetamab: 0.01 mg/kg, 0.06 mg/kg, 0.4 mg/kg, then 0.8 mg/kg FFD and q2wk SC Daratumumab/hyaluronidase: C1+2: 1800 mg weekly, C3–6: 1800 mg q2wk, C7+: 1800 mg q4wk	Talquetamab: 0.01 mg/kg, 0.06 mg/kg, 0.4 mg/kg, then 0.8 mg/kg FFD and q2wk SC Daratumumab/hyaluronidase: C1-2: 1800 mg weekly, C3–6: 1800 mg q2wk, C7+: 1800 mg q4wk Pomalidomide: C2 +: 2 mg QD on D1–21 (then 7 days off)
PREMEDICATIONS	Acetaminophen 650-1,000 mg, diphenhydramine 50 mg/equivalent, and dexamethasone 16 mg during C1 step-up dosing/FFD per study protocol	Acetaminophen 650–1,000 mg; diphenhydramine 50 mg/equivalent; dexamethasone 16 mg/equivalent before each SUD and FFD	Acetaminophen 650–1,000 mg; diphenhydramine 50 mg/equivalent; dexamethasone 16 mg/equivalent before each SUD and FFD
HOSPITALIZATION/OBSERVATION	Trial/reference required 48-hour hospitalization after all SUDs and FFD.	Hospitalization for 48 hours after every dose in its SUD schedule	Hospitalization for 48 hours after every dose in its SUD schedule
CRS INCIDENCE BY GRADE	79% overall: G1–2 77%, G3 2%; no G4–5 reported	58.4% overall: G1 48.9%, G2 8.8%; no G≥3 reported	67.8% overall: G1 55.8%, G2 11.2%; no G≥3 reported
CRS ONSET/PATTERN	Most events during SUD and early cycles; median onset two days	Most events during SUD; median onset not reported	Most events during SUD; median onset not reported
CRS DURATION	Median two days; 98% recovered, 1% with sequelae, 1% incomplete recovery	Median two days (1–57) across talquetamab combination groups; nearly all resolved	Median two days (1–57) across talquetamab combination groups; nearly all resolved
NEUROLOGIC PROBLEMS: INCIDENCE	ICANS 3% (one G3 event); broader neurologic-toxicity incidence not reported	ICANS 1.8%; grade distribution not reported; broader neurologic-toxicity incidence not reported	ICANS 2.9%; three G3 events; broader neurologic-toxicity incidence not reported
NEUROLOGIC PROBLEMS: ONSET/PATTERN	All ICANS during SUD; median onset 2.5 days	Onset not reported	Onset not reported
NEUROLOGIC PROBLEMS: DURATION	Median ICANS duration three days; all recovered	Duration not reported; events resolved	Duration not reported; all reported G3 events resolved
ANY GRADE AES/LABS ≥20%	AEs – infections 89%; CRS 79%; taste changes 65%; non-rash skin events 61%; anemia 56%; nail-related events 52%; pyrexia 51%; diarrhea 48%; cough 45%; dry mouth 43%; COVID-19 40%; rash 39%; pneumonia 36%; weight decreased 34%; fatigue 28% Labs – neutropenia 73%; thrombocytopenia 43%	AEs – infections 84.3%; taste changes 74.8%; hypogammaglobulinemia 70.1%; non-rash skin events 64.6%; CRS 58.4%; nail-related events 57.3%; pyrexia 40.9%; anemia 39.1%; rash 39.1%; weight decreased 38.3%; lymphopenia 29.9%; diarrhea 29.6%; dry mouth 26.6%; cough 25.5%; fatigue 21.9% Labs – neutropenia 40.9%; thrombocytopenia 33.9%; hypokalemia 20.1%	AEs – infections 87.3%; hypogammaglobulinemia 81.5%; taste changes 72.8%; non-rash skin events 69.2%; CRS 67.8%; nail-related events 56.2%; anemia 49.3%; pyrexia 46.0%; weight decreased 45.7%; rash 38.0%; diarrhea 37.7%; fatigue 30.1%; nausea 28.6%; dry mouth 27.9%; cough 26.8% Labs – neutropenia 84.1%; thrombocytopenia 49.3%; lymphopenia 35.9%; leukopenia 34.1%; hypokalemia 24.6%
GRADE ≥3 AES/LABS ≥10%	AEs – infections 64%; anemia 38%; pneumonia 20%; COVID-19 18% Labs – neutropenia 68%; thrombocytopenia 30%	AEs – infections 29.2%; anemia 15.0% Labs – neutropenia 29.2%; lymphopenia 24.8%; thrombocytopenia 13.1%	AEs – infections 37.7%; anemia 23.9%; pneumonia 13.8% Labs – neutropenia 76.4%; lymphopenia 31.2%; thrombocytopenia 23.9%; leukopenia 22.8%
REMS PROGRAM	Yes – component requirements under TECVAYLI and TALVEY REMS	Yes – TALVEY component requirement under TECVAYLI and TALVEY REMS	Yes – TALVEY component requirement under TECVAYLI and TALVEY REMS; pomalidomide under the pomalidomide REMS

TEAR-OUT TABLE FOR CLINICAL REFERENCE

TABLE 7: UVEAL MELANOMA — HLA-A*02:01-POSITIVE UNRESECTABLE OR METASTATIC (AS OF JULY 2026)

CLINICAL ELEMENT	TEBENTAFUSP-TEBN (KIMMTRAK®) FDA-APPROVED
MANUFACTURER	Immunocore Commercial LLC.
TARGET/ROUTE	gp100 peptide-HLA×CD3; IV
PATIENT SELECTION/TRIAL	Confirm HLA-A*02:01 genotype; IMCgp100-202
SCHEDULE/SUD	20 mcg D1; 30 mcg D8; 68 mcg D15 FFD; then 68 mcg weekly
PREMEDICATIONS	N/A
HOSPITALIZATION/OBSERVATION	First three infusions: administer in appropriate healthcare setting and monitor during infusion and ≥16 hours afterward. If no G≥2 hypotension during/after third infusion, later doses may be given ambulatory with ≥30-minute monitoring
CRS INCIDENCE BY GRADE	89% overall; approximately G1 12%, G2 76%, G3–4 0.8%; no G5 reported. CRS G≥2 occurred in 77%
CRS ONSET/PATTERN	84% of CRS episodes started on the infusion day; 60% experienced G≥2 CRS with more than one infusion
CRS DURATION	Median time to resolution two days among resolved cases
NEUROLOGIC PROBLEMS	ICANS and neurologic toxicity syndromes are not reported as identified safety signals
ANY GRADE AES/LABS ≥20%	AEs — CRS 89%; rash 83%; pyrexia 76%; pruritus 69%; fatigue 64%; nausea 49%; chills 48%; abdominal pain 45%; edema 45%; hypotension 39%; dry skin 31%; headache 31%; vomiting 30%; skin hypopigmentation 28%; diarrhea 25%; erythema 24%; arthralgia 22%; hair-color changes 20% Labs — lymphocyte count decreased 91%; creatinine increased 87%; glucose increased 66%; AST increased 55%; ALT increased 52%; hemoglobin decreased 51%; phosphate decreased 51%; albumin decreased 47%; calcium decreased 45%; lipase increased 37%; magnesium decreased 34%; alkaline phosphatase increased 34%; sodium decreased 30%; potassium increased 29%; bilirubin increased 27%; amylase increased 23%
GRADE ≥3 AES/LABS ≥10%	AEs — rash 18% Labs — lymphocyte count decreased 56%; lipase increased 15%; AST increased 13%; phosphate decreased 11%
REMS PROGRAM	No
INITIAL U.S. APPROVAL	2022

REFERENCES

1. Lunsumio. Prescribing information. Genentech, Inc.; 2026. Accessed July 16, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761263s010lbl.pdf.

2. Lunsumio Velo. Prescribing information. Genentech, Inc.; 2026. Accessed July 16, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761263s006lbl.pdf.

3. Epkinly. Prescribing information. Genmab US, Inc. and AbbVie Inc.; 2026. Accessed July 16, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761324s011lbl.pdf.

4. Columvi. Prescribing information. Genentech, Inc.; 2026. Accessed July 16, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761309s007lbl.pdf.

5. Tecvayli. Prescribing information. Janssen Biotech, Inc.; 2026. Accessed July 16, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761291s018lbl.pdf.

6. Talvey. Prescribing information. Janssen Biotech, Inc.; 2025. Accessed July 16, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761342s016lbl.pdf.

7. Elrexfio. Prescribing information. Pfizer Inc.; revised February 2026. Accessed July 16, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761345s007lbl.pdf.

8. Lynozyfic. Prescribing information. Regeneron Pharmaceuticals, Inc.; 2025. Accessed July 16, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761400s000lbl.pdf.

9. Blincyto. Prescribing information. Amgen Inc.; 2026. Accessed July 16, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/125557s032lbl.pdf.

10. Imdelltra. Prescribing information. Amgen Inc.; 2025. Accessed July 16, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761344s001lbl.pdf.

11. Kimmtrak. Prescribing information. Immunocore Commercial LLC; 2024. Accessed July 16, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761228s003lbl.pdf.

12. Brody JD, Jørgensen J, Belada D, et al. Epcoritamab plus GemOx in transplant-ineligible relapsed/refractory DLBCL: results from the EPCORE NHL-2 trial. *Blood*. 2025;145(15):1621-1631. doi:10.1182/blood.2024026830.

13. Abramson JS, Ku M, Hertzberg M, et al. Glofitamab plus gemcitabine and oxaliplatin (GemOx) versus rituximab-GemOx for relapsed or refractory diffuse large B-cell lymphoma (STARGLO): a global phase 3, randomised, open-label trial. *Lancet*. 2024;404(10466):1940-1954. doi:10.1016/S0140-6736(24)01774-4.

14. Cohen YC, Magen H, Gatt M, et al. Talquetamab plus teclistamab in relapsed or refractory multiple myeloma. *N Engl J Med*. 2025;392(2):138-149. doi:10.1056/NEJMoa2406536.

15. Mina R, Beksac M, Rodríguez-Otero P, et al. Talquetamab-daratumumab in relapsed or refractory myeloma. *N Engl J Med*. Published online June 13, 2026. doi:10.1056/NEJMoa2604657.