Press Releases

April 01, 2022

Yescarta® Receives U.S. FDA Approval as First CAR T-cell Therapy for Initial Treatment of Relapsed or Refractory Large B-cell Lymphoma (LBCL)

-- First LBCL Treatment to Improve Upon Standard of Care in Nearly 30 Years --

-- Landmark ZUMA-7 Study Demonstrated Patients on Yescarta Were 2.5 Times More Likely to Be Alive at Two Years Without Cancer Progression or Need for Additional Cancer Treatment --

-- Yescarta is First CAR T-cell Therapy to Receive NCCN Treatment Guideline Category 1 Recommendation --

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite, a Gilead Company (Nasdaq: GILD), today announced the U.S. Food and Drug Administration (FDA) has approved Yescarta® (axicabtagene ciloleucel) CAR T-cell therapy for adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. Yescarta demonstrated a clinically meaningful and statistically significant improvement in event-free survival (EFS; hazard ratio 0.398; P< 0.0001) over the current standard of care (SOC) that has been in place for decades. EFS was determined by blinded central review and defined as the time from randomization to the earliest date of disease progression, commencement of new lymphoma therapy, or death from any cause. Additionally, 2.5 times more patients receiving Yescarta (40.5%) were alive at two years without disease progression or need for additional cancer treatment, after their one-time infusion of Yescarta vs. SOC (16.3%), and the median EFS was four-fold greater (8.3 months vs. 2.0 months) with Yescarta vs. SOC. Yescarta is also being reviewed by global regulatory authorities for additional indications inclusive of the ZUMA-7 patient population. ZUMA-7 is considered a landmark trial for being the first and largest trial of its kind, with the longest follow-up.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20220401005519/en/

Earlier this month, the National Comprehensive Cancer Network (NCCN) updated its Clinical Practice Guidelines in Oncology for B-cell Lymphomas to include Yescarta for “Relapsed

disease <12 mo or Primary Refractory disease" under Diffuse Large B-cell Lymphoma (DLBCL) as a Category 1 recommendation. Yescarta is the first CAR T-cell therapy to receive a NCCN Category 1 recommendation. NCCN defines Category 1 as recommendations based upon high-level evidence with uniform NCCN consensus that the intervention is appropriate.

Christi Shaw, Chief Executive Officer of Kite: "Kite started with a very bold goal: creating the hope of survival through cell therapy. Today's FDA approval brings that hope to more patients by enabling the power of CAR T-cell therapy to be used earlier in the treatment journey. This milestone has been years in the making. On behalf of the entire Kite community, we would like to thank the patients and physicians who have been on this journey with us. You are what drives us every day to explore the full potential of cell therapy."

CAR T-cell therapies are individually made starting from a patient's own white blood cells, called T-cells. The cells are removed through a process similar to donating blood and sent to Kite's specialized manufacturing facilities where they are engineered to target the patient's cancer, expanded, and then returned to the hospital for infusion back into the patient. Referring physicians and patients can immediately begin accessing Yescarta CAR T-cell therapy for this new FDA-approved indication through Kite's 112 authorized treatment c enters across the U.S.

Frederick L. Locke, MD, ZUMA-7 Principal Investigator and Co-Leader of the Immuno-Oncology Program at Moffitt Cancer Center, Tampa, Florida: "Today's approval marks an exciting new standard of care. The ZUMA-7 trial enabled us to look at the broader picture of what happens to patients after a decision is made to follow a particular treatment path. What we found was that axi-cel resulted in three times as many patients receiving treatment with curative intent (CAR T-cell therapy), and an overall better outcome for patients than the previous standard of care. Additionally, we have now amassed significant experience with CAR T-cell therapy to better manage or prevent side-effects, making this treatment more accessible for older patients and those with medical conditions for whom the standard of care might be difficult."

SOC therapy for this patient population has historically been a multi-step process expected to end with a stem cell transplant. The process starts with chemoimmunotherapy, and if a patient responds to and can tolerate further treatment, they move on to high-dose chemotherapy (HDT) followed by a stem cell transplant (ASCT).

Jason Westin, MD, MS, FACP, ZUMA-7 Principal Investigator, Director, Lymphoma Clinical Research, and Associate Professor, Department of Lymphoma/Myeloma at The

University of Texas MD Anderson Cancer Center: "Definitive clinical trial results such as these do not come along often and should drive a paradigm shift in how patients with relapsed or refractory LBCL are treated moving forward. Patients who do not respond to or relapse after initial treatment should quickly be referred to a CAR T-cell therapy authorized treatment center for evaluation."

Kite CAR T-cell therapy products are widely covered by commercial and government insurance programs in the U.S. Kite has also invested in expansion of manufacturing capacity ahead of today's FDA decision to support patient access.

Lee Greenberger, PhD, Chief Scientific Officer of The Leukemia & Lymphoma Society (LLS): "LLS was an early supporter of CAR T-cell therapy research, and to be able to see this innovative advance become available as an earlier line of treatment is truly remarkable. Current standard of care is a difficult process for patients, and no one knows at the start who will make it to stem cell transplant. With today's FDA decision, patients will have earlier access to this potentially curative treatment."

Yescarta was initially approved by the FDA in 2017 based on the ZUMA-1 trial for a smaller population of LBCL patients who failed two or more lines of therapy. The ZUMA-1 trial has recently reported durable 5-year survival results, with Yescarta showing 42.6% of study patients alive at 5 years and that 92% of those patients alive at 5 years have needed no additional cancer treatment at this important milestone.

As the only company dedicated exclusively to the research, development, commercialization, and manufacturing of cell therapy on a global scale, Kite has all functions critical to cell therapy vertically integrated. This structure enables the continual refinement and support of the highly specialized and complex end-to-end processes needed to support and improve upon patient outcomes with CAR T-cell therapy.

About ZUMA-7 Study

The FDA approval of Yescarta CAR T-cell therapy for adult patients with large B-cell lymphoma (LBCL) that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy is based on results from the ZUMA-7 study. Patients had not yet received treatment for relapsed or refractory lymphoma and were potential candidates for autologous stem cell transplant (ASCT). Results were presented in a Plenary session at the American Society of Hematology's (ASH) Annual Meeting & Exposition in December 2021 and simultaneously published in the *NewEngland Journal of Medicine* (NEJM).

ZUMA-7 is a randomized, open-label, global, multicenter, Phase 3 study evaluating the safety and efficacy of Yescarta versus current standard of care (SOC) for second-line

safety and efficacy of Yescarta versus current standard of care (SOC) for second-line therapy (platinum-based salvage combination chemoimmunotherapy regimen followed by high-dose therapy [HDT] and ASCT in those who respond to salvage chemotherapy) in adult patients with relapsed or refractory LBCL within 12 months of first-line therapy. In the study, 359 patients in 77 centers around the world were randomized (1:1) to receive a single infusion of Yescarta or current SOC second-line therapy. The primary endpoint is event-free survival (EFS) as determined by blinded central review and defined as the time from randomization to the earliest date of disease progression per Lugano Classification, commencement of new lymphoma therapy, or death from any cause. Key secondary endpoints include objective response rate (ORR) and overall survival (OS). Additional secondary endpoints include patient reported outcomes (PROs) and safety.

Yescarta demonstrated a 2.5-fold increase in patients who were alive at two years and did not experience cancer progression or require the need for additional cancer treatment (40.5% vs. 16.3%) and a four-fold greater median EFS (8.3 mo. vs. 2.0 mo.) compared to SOC (hazard ratio 0.398; 95% CI: 0.308-0.514, P<0.0001). In addition to being the largest and longest study of its kind, ZUMA-7 study participants on the Yescarta arm did not receive additional bridging chemotherapy that could have potentially confounded results.

Nearly three times as many patients randomized to Yescarta ultimately received the definitive CAR T-cell therapy treatment (94%) versus those randomized to SOC (35%) who received on-protocol HDT+ASCT. More patients responded to Yescarta (ORR: 83% vs. 50%, odds ratio: 5.31 [95% CI: 3.1-8.9; P<0.0001) and achieved a complete response (CR) with Yescarta (CR rate: 65% vs. 32%) than with SOC. At a pre-specified interim analysis at the time of the primary EFS analysis, OS has not met the criteria for statistical significance, but favored Yescarta.

Fifty-five percent of patients in the SOC arm subsequently received CD19-directed CAR T-cell therapy off study.

In the study, Yescarta had a safety profile that was consistent with previous studies. Among the 168 Yescarta-treated patients evaluable for safety, Grade ≥3 cytokine release syndrome (CRS) and neurologic events were observed in 7% and 25% of patients, respectively. In the SOC arm, 83% of patients had high grade events, mostly cytopenias (low blood counts).

The Yescarta U.S. Prescribing Information has a BOXED WARNING for the risks of CRS and neurologic toxicities, and Yescarta is approved with a Risk Evaluation and Mitigation Strategy (REMS) due to these risks; see below for Important Safety Information.

About LBCL

Globally, LBCL is the most common type of non-Hodgkin lymphoma (NHL). In the United States, more than 18,000 people are diagnosed with LBCL each year. About 30-40% of

States, more than 18,000 people are diagnosed with LBCL each year. About 30-40% of patients with LBCL will need second-line treatment, as their cancer will either relapse (return) or become refractory (not respond) to initial treatment.

About Yescarta

Please see full Prescribing Information, including **BOXED WARNING** and Medication Guide.

YESCARTA is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
- Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Limitations of Use: YESCARTA is not indicated for the treatment of patients with primary central nervous system lymphoma.

- Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

U.S. IMPORTANT SAFETY INFORMATION

BOXED WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITIES

- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving YESCARTA. Do not administer YESCARTA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.**
- **Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving YESCARTA, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with YESCARTA. Provide supportive care and/or corticosteroids as needed.**
- **YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program.**

CYTOKINE RELEASE SYNDROME (CRS)

CRS, including fatal or life-threatening reactions, occurred. CRS occurred in 90% (379/422) of patients with non-Hodgkin lymphoma (NHL), including ≥ Grade 3 in 9%. CRS occurred in 93% (256/276) of patients with large B-cell lymphoma (LBCL), including ≥ Grade 3 in 9%. Among patients with LBCL who died after receiving YESCARTA, 4 had ongoing CRS events

at the time of death. For patients with LBCL in ZUMA-1, the median time to onset of CRS was 2 days following infusion (range: 1-12 days) and the median duration was 7 days (range:

2-58 days). For patients with LBCL in ZUMA-7, the median time to onset of CRS was 3 days following infusion (range: 1-10 days) and the median duration was 7 days (range: 2-43 days). CRS occurred in 84% (123/146) of patients with indolent non-Hodgkin lymphoma (iNHL) in ZUMA-5, including ≥ Grade 3 in 8%. Among patients with iNHL who died after receiving YESCARTA, 1 patient had an ongoing CRS event at the time of death. The median time to onset of CRS was 4 days (range: 1-20 days) and median duration was 6 days (range: 1-27 days) for patients with iNHL.

Key manifestations of CRS (≥ 10%) in all patients combined included fever (85%), hypotension (40%), tachycardia (32%), chills (22%), hypoxia (20%), headache (15%), and fatigue (12%). Serious events that may be associated with CRS include cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), renal insufficiency, cardiac failure, respiratory failure, cardiac arrest, capillary leak syndrome, multi-organ failure, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome.

The impact of tocilizumab and/or corticosteroids on the incidence and severity of CRS was assessed in 2 subsequent cohorts of LBCL patients in ZUMA-1. Among patients who received tocilizumab and/or corticosteroids for ongoing Grade 1 events, CRS occurred in 93% (38/41), including 2% (1/41) with Grade 3 CRS; no patients experienced a Grade 4 or 5 event. The median time to onset of CRS was 2 days (range: 1-8 days) and the median duration of CRS was 7 days (range: 2-16 days). Prophylactic treatment with corticosteroids was administered to a cohort of 39 patients for 3 days beginning on the day of infusion of YESCARTA. Thirty-one of the 39 patients (79%) developed CRS and were managed with tocilizumab and/or therapeutic doses of corticosteroids with no patients developing ≥ Grade 3 CRS. The median time to onset of CRS was 5 days (range: 1-15 days) and the median duration of CRS was 4 days (range: 1-10 days). Although there is no known mechanistic explanation, consider the risk and benefits of prophylactic corticosteroids in the context of pre-existing comorbidities for the individual patient and the potential for the risk of Grade 4 and prolonged neurologic toxicities.

Ensure that 2 doses of tocilizumab are available prior to YESCARTA infusion. Monitor patients for signs and symptoms of CRS at least daily for 7 days at the certified healthcare facility, and for 4 weeks thereafter. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids as indicated.

NEUROLOGIC TOXICITIES

Neurologic toxicities (including immune effector cell-associated neurotoxicity syndrome) that were fatal or life-threatening occurred. Neurologic toxicities occurred in 78% (330/422)

of all patients with NHL receiving YESCARTA, including ≥ Grade 3 in 25%. Neurologic toxicities occurred in 87% (94/108) of patients with LBCL in ZUMA-1, including ≥ Grade 3 in 31% and in 74% (124/168) of patients in ZUMA-7 including ≥ Grade 3 in 25%. The median time to onset was 4 days (range: 1-43 days) and the median duration was 17 days for patients with LBCL in ZUMA-1. The median time to onset for neurologic toxicity was 5 days (range:1- 133 days) and median duration was 15 days in patients with LBCL in ZUMA-7. Neurologic toxicities occurred in 77% (112/146) of patients with iNHL, including ≥ Grade 3 in 21%. The median time to onset was 6 days (range: 1-79 days) and the median duration was 16 days. Ninety-eight percent of all neurologic toxicities in patients with LBCL and 99% of all neurologic toxicities in patients with iNHL occurred within the first 8 weeks of YESCARTA infusion. Neurologic toxicities occurred within the first 7 days of infusion for 87% of affected patients with LBCL and 74% of affected patients with iNHL.

The most common neurologic toxicities (≥ 10%) in all patients combined included encephalopathy (50%), headache (43%), tremor (29%), dizziness (21%), aphasia (17%), delirium (15%), and insomnia (10%). Prolonged encephalopathy lasting up to 173 days was noted. Serious events, including aphasia, leukoencephalopathy, dysarthria, lethargy, and seizures occurred. Fatal and serious cases of cerebral edema and encephalopathy, including late-onset encephalopathy, have occurred.

The impact of tocilizumab and/or corticosteroids on the incidence and severity of neurologic toxicities was assessed in 2 subsequent cohorts of LBCL patients in ZUMA-1. Among patients who received corticosteroids at the onset of Grade 1 toxicities, neurologic toxicities occurred in 78% (32/41) and 20% (8/41) had Grade 3 neurologic toxicities; no patients experienced a Grade 4 or 5 event. The median time to onset of neurologic toxicities was 6 days (range: 1-93 days) with a median duration of 8 days (range: 1-144 days). Prophylactic treatment with corticosteroids was administered to a cohort of 39 patients for 3 days beginning on the day of infusion of YESCARTA. Of those patients, 85% (33/39) developed neurologic toxicities, 8% (3/39) developed Grade 3, and 5% (2/39) developed Grade 4 neurologic toxicities. The median time to onset of neurologic toxicities was 6 days (range: 1-274 days) with a median duration of 12 days (range: 1-107 days). Prophylactic corticosteroids for management of CRS and neurologic toxicities may result in higher grade of neurologic toxicities or prolongation of neurologic toxicities, delay the onset and decrease the duration of CRS.

Monitor patients for signs and symptoms of neurologic toxicities at least daily for 7 days at the certified healthcare facility, and for 4 weeks thereafter, and treat promptly.

REMS

Because of the risk of CRS and neurologic toxicities, YESCARTA is available only through a restricted program called the YESCARTA and TECARTUS REMS Program which requires that: Healthcare facilities that dispense and administer YESCARTA must be enrolled and comply with the REMS requirements and must have on-site, immediate access to a minimum of 2 doses of tocilizumab for each patient for infusion within 2 hours after YESCARTA infusion, if needed for treatment of CRS. Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer YESCARTA are trained about the management of CRS and neurologic toxicities. Further information is available at www.YescartaTecartusREMS.com or 1-844-454-KITE (5483).

HYPERSENSITIVITY REACTIONS

Allergic reactions, including serious hypersensitivity reactions or anaphylaxis, may occur with the infusion of YESCARTA.

SERIOUS INFECTIONS

Severe or life-threatening infections occurred. Infections (all grades) occurred in 45% of patients with NHL. ≥ Grade 3 infections occurred in 17% of patients, including ≥ Grade 3 infections with an unspecified pathogen in 12%, bacterial infections in 5%, viral infections in 3%, and fungal infections in 1%. YESCARTA should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after infusion and treat appropriately. Administer prophylactic antimicrobials according to local guidelines.

Febrile neutropenia was observed in 36% of all patients with NHL and 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.

In immunosuppressed patients, including those who have received YESCARTA, life-threatening and fatal opportunistic infections including disseminated fungal infections (e.g., candida sepsis and aspergillus infections) and viral reactivation (e.g., human herpes virus-6 [HHV-6] encephalitis and JC virus progressive multifocal leukoencephalopathy [PML]) have been reported. The possibility of HHV-6 encephalitis and PML should be considered in immunosuppressed patients with neurologic events and appropriate diagnostic evaluations should be performed.

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, including YESCARTA. Perform screening for HBV, HCV, and HIV in accordance with clinical

including YESCARTA. Perform screening for HBV, HCV, and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

PROLONGED CYTOPENIAS

Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and YESCARTA infusion. ≥ Grade 3 cytopenias not resolved by Day 30 following YESCARTA infusion occurred in 39% of all patients with NHL and included neutropenia (33%), thrombocytopenia (13%), and anemia (8%). Monitor blood counts after infusion.

HYPOGAMMAGLOBULINEMIA B-cell aplasia and hypogammaglobulinemia can occur. Hypogammaglobulinemia was reported as an adverse reaction in 14% of all patients with NHL. Monitor immunoglobulin levels after treatment and manage using infection precautions, antibiotic prophylaxis, and immunoglobulin replacement. The safety of immunization with live viral vaccines during or following YESCARTA 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 YESCARTA treatment, and until immune recovery following treatment.

SECONDARY MALIGNANCIES

Secondary malignancies may develop. Monitor life-long for secondary malignancies. In the event that one occurs, contact Kite at 1-844-454-KITE (5483) to obtain instructions on patient samples to collect for testing.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Due to the potential for neurologic events, including altered mental status or seizures, patients are at risk for altered or decreased consciousness or coordination in the 8 weeks following YESCARTA infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

ADVERSE REACTIONS

The most common non-laboratory adverse reactions (incidence ≥ 20%) in patients with LBCL in ZUMA-7 included fever, CRS, fatigue, hypotension, encephalopathy, tachycardia, diarrhea, headache, musculoskeletal pain, nausea, febrile neutropenia, chills, cough, infection with unspecified pathogen, dizziness, tremor, decreased appetite, edema, hypoxia, abdominal pain, aphasia, constipation, and vomiting.

The most common adverse reactions (incidence ≥ 20%) in patients with LBCL in ZUMA-1 included CRS, fever, hypotension, encephalopathy, tachycardia, fatigue, headache,

decreased appetite, chills, diarrhea, febrile neutropenia, infections with pathogen unspecified, nausea, hypoxia, tremor, cough, vomiting, dizziness, constipation, and cardiac arrhythmias.

The most common non-laboratory adverse reactions (incidence ≥ 20%) in patients with iNHL in ZUMA-5 included fever, CRS, hypotension, encephalopathy, fatigue, headache, infections with pathogen unspecified, tachycardia, febrile neutropenia, musculoskeletal pain, nausea, tremor, chills, diarrhea, constipation, decreased appetite, cough, vomiting, hypoxia, arrhythmia, and dizziness.

About Kite

Kite, a Gilead Company, is a global biopharmaceutical company based in Santa Monica, California, with manufacturing operations in North America and Europe. Kite's singular focus is cell therapy to treat and potentially cure cancer. As the cell therapy leader, Kite has more approved CAR T indications to help more patients than any other company. For more information on Kite, please visit www.kitepharma.com.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

Forward Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the possibility of unfavorable results from ongoing or additional clinical trials involving Yescarta; Kite's ability to initiate, progress or complete clinical trials within currently anticipated timelines or at all, including those involving Yescarta; Kite's ability to receive regulatory approvals in a timely manner or at all, including additional regulatory approvals of Yescarta, and the risk that any such approvals may be subject to significant limitations on use; the risk that physicians may not see the benefits of prescribing Yescarta; and any assumptions underlying any of the foregoing. These and other risks, uncertainties and other factors are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially

These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to Kite and Gilead, and Kite and Gilead assume no obligation and disclaim any intent to update any such forward-looking statements.

*U.S. Prescribing Information for Yescarta including **BOXED WARNING**, is available at www.kitepharma.com and www.gilead.com.*

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