ALUNBRIG®
BRIGATINIB
180mg | 90mg | 30mg
TABLETS

ALUNBRIG SMART™ Free Trial Program Request Form

FAX PAGES 1 & 2 TO: 1-857-465-7247 **PHONE:** 1-833-618-2786

1. PRESCRIBING PHYSICIAN INFORMATION

Name (First, Last): _____ State License #: _____ NPI #: _____

Street Address: _____ City: _____ State: _____ ZIP: _____

Office Contact: _____ Telephone: _____ Fax: _____ Email: _____

2. PATIENT INFORMATION

Patient Name (First, Middle, Last): _____ ❑ Male ❑ Female

DOB (MM/DD/YYYY): _____ Email: _____

Address: _____ City: _____ State: _____ ZIP: _____

Mobile Telephone (M): _____ Work Telephone (W): _____ Home Telephone (H): _____

Preferred Telephone: ❑ M ❑ W ❑ H OK to leave message? ❑ Yes ❑ No

3. CAREGIVER INFORMATION

Name (First, Last): _____

Mobile Telephone (M): _____ Work Telephone (W): _____ Home Telephone (H): _____

Preferred Telephone: ❑ M ❑ W ❑ H OK to leave message? ❑ Yes ❑ No

4. ALUNBRIG PRESCRIPTION REQUEST

Prescription: **ALUNBRIG** ICD-10: _____

DISPENSE (Select One)
❑ **1 starter pack (7 count of 90-mg tablets and 23 count of 180-mg tablets)**
❑ **5 bottles (30 count of 30-mg tablets)**
❑ **2 bottles (30 count of 90-mg tablets)**

❑ Dosing instructions: _____

Previous therapies, if any: _____

Allergies: ❑ No known drug allergies ❑ Patient allergies (drug and non-drug): _____

5. PRESCRIBER AUTHORIZATION

By signing below, I certify that this prescription is on-label, that the patient is new to ALUNBRIG treatment, and I have read and agree to the Program Terms. I understand that this program is intended for the evaluation of ALUNBRIG with my eligible patient to determine whether ALUNBRIG is right for them. I authorize the agents of Takeda to use the above information to provide the ALUNBRIG SMART™ Free Trial Program to my patient. I understand that the agents of Takeda will keep this information confidential and will use it only for the ALUNBRIG SMART™ Free Trial Program. This usage may include a follow-up survey about my patient's and/or my experiences with the ALUNBRIG SMART™ Free Trial Program and ALUNBRIG. Neither I nor my agents will submit any portion of the ALUNBRIG SMART™ Free Trial Program or administration services for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly. The information you provide will be used to administer support services and information on Takeda's programs, therapies, services to you and your patient, and clinical studies. We may share the information provided with our partners who facilitate the verification and delivery of this information. If you ever decide that you do not wish to receive information from us regarding our therapies and services, contact us at 1-833-618-2786.

SIGN HERE Prescriber Signature (Required): _____ Date: _____

Stamps not acceptable DISPENSE AS WRITTEN

ATTENTION New York State Prescribers: Prescribers in New York State must submit prescription on an original NY State prescription blank. For all other states, if not faxed, the prescription must be on a state-specific blank if applicable for your state. **Any prescription written must match the selected dispense option above.**

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6. PATIENT AUTHORIZATION AND PROGRAM TERMS CONFIRMATION

By signing this Authorization, I authorize my healthcare providers and any applicable pharmacy to disclose my protected health information, including, but not limited to, personal information related to my medical condition, treatment, and care management, as well as all information provided on this form including contact and any prescription information ("Personal Health Information"), to Takeda Pharmaceuticals, U.S.A., Inc. ("TPUSA"), its affiliates, and their representatives, agents, and contractors ("Company") in connection with the Company's provision of product, supplies, and/or services under this free trial program or as directed by me at a later date for other purposes. I understand that the Company may communicate with me by mail, email, or telephone about my medical condition, treatment, and care management. I understand I may be contacted to participate in a follow-up survey about my experience in this free trial program. I understand that once disclosed to the Company, my Personal Health Information disclosed under this Authorization may no longer be protected by federal privacy law, including HIPAA. This Authorization will expire within five (5) years from today's date, unless a shorter period is provided for by state law. I understand that I may revoke this Authorization at any time by calling 1-833-618-2786 or by writing PO Box 4280, Gaithersburg, MD 20885-4280, except to the extent that action has already been taken in reliance on this Authorization.

SIGN HERE Signature of Patient (Required): _____ Date: _____

SIGN HERE Legal Representative (If applicable): _____ Date: _____

❑ I have read, understand, and agree to the Program Terms at the top of page 3.

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PROGRAM TERMS

- This free trial offer is solely intended to allow new patients to try ALUNBRIG and to determine with their healthcare provider whether ALUNBRIG is right for them. There is no obligation to continue use of ALUNBRIG after the free trial has been completed
- This free trial prescription is valid for one time only with no refills. For any future use, the patient must obtain a new prescription for ALUNBRIG
- To be eligible: 1) patient must be an adult with a diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test; 2) be a new patient not currently using ALUNBRIG and who has not previously enrolled in the ALUNBRIG SMART™ Free Trial Program
- The ALUNBRIG SMART™ Free Trial Program cannot be exported or transferred in exchange for money, other property, and services
- **No portion of the ALUNBRIG SMART™ Free Trial Program or administration services may be submitted for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly**
- This program is only valid for residents of the United States, excluding Puerto Rico and other US territories
- Takeda Pharmaceuticals, U.S.A., Inc. reserves the right to change or discontinue this program at any time without notice
- This is not a financial assistance nor cost savings program

INSTRUCTIONS FOR COMPLETION OF FORM

1. PRESCRIBING PHYSICIAN INFORMATION and PATIENT INFORMATION

- Fill out completely
- **Do not** submit to Takeda any documentation of labs, clinical history, or other documents supporting the prior authorization process including a separate prescription

2. ALUNBRIG PRESCRIPTION REQUEST and PRESCRIBER AUTHORIZATION

- This is a prescription; a physician's signature and date are required

3. PATIENT AUTHORIZATION and PROGRAM TERMS CONFIRMATION

- The patient signature is required to allow personal health information to be shared by third parties to Takeda to facilitate access to ALUNBRIG (fulfilling and coordinating delivery of medication, etc)

4. FAX PAGES 1 & 2 TO: 1-857-465-7247

INDICATION

ALUNBRIG is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Interstitial Lung Disease (ILD)/Pneumonitis

Severe, life-threatening, and fatal pulmonary adverse reactions consistent with interstitial lung disease (ILD)/pneumonitis have occurred with ALUNBRIG. In ALTA 1L, ILD/pneumonitis occurred in 5.1% of patients receiving ALUNBRIG. ILD/pneumonitis occurred within 8 days of initiation of ALUNBRIG in 2.9% of patients, with Grade 3 to 4 reactions occurring in 2.2% of patients. In ALTA, ILD/pneumonitis occurred in 3.7% of patients in the 90 mg group (90 mg once daily) and 9.1% of patients in the 90⟶180 mg group (180 mg once daily with 7-day lead-in at 90 mg once daily). Adverse reactions consistent with possible ILD/pneumonitis occurred within 9 days of initiation of ALUNBRIG (median onset was 2 days) in 6.4% of patients, with Grade 3 to 4 reactions occurring in 2.7% of patients. Monitor for new or worsening respiratory symptoms (dyspnea, cough, etc.), particularly during the first week of initiating ALUNBRIG. Withhold ALUNBRIG in any patient with new or worsening respiratory symptoms, and promptly evaluate for ILD/pneumonitis or other causes of respiratory symptoms (e.g., pulmonary embolism, tumor progression, and infectious pneumonia). For Grade 1 or 2 ILD/pneumonitis, either resume ALUNBRIG with dose reduction according to Table 1 of the full Prescribing Information after recovery to baseline or permanently discontinue ALUNBRIG. Permanently discontinue ALUNBRIG forGrade 3 or 4 ILD/pneumonitis or recurrence of Grade 1 or 2 ILD/pneumonitis.

Hypertension

In ALTA 1L, hypertension was reported in 32% of patients receiving ALUNBRIG; 13% of patients experienced Grade 3 hypertension. In ALTA, hypertension was reported in 11% of patients in the 90 mg group and 21% of patients in the 90⟶180 mg group. Grade 3 hypertension occurred in 5.9% of patients overall. Control blood pressure prior to treatment with ALUNBRIG. Monitor blood pressure after 2 weeks and at least monthly thereafter during treatment with ALUNBRIG. Withhold ALUNBRIG for Grade 3 hypertension despite optimal antihypertensive therapy. Upon resolution or improvement to Grade 1, resume ALUNBRIG at the same dose. Consider permanent discontinuation of treatment with ALUNBRIG for Grade 4 hypertension or recurrence of Grade 3 hypertension. Use caution when administering ALUNBRIG in combination with antihypertensive agents that cause bradycardia.

Bradycardia

In ALTA 1L, heart rates less than 50 beats per minute (bpm) occurred in 8.1% of patients receiving ALUNBRIG; one patient (0.7 %) experienced Grade 3 bradycardia. In ALTA, heart rates less than 50 beats per minute (bpm) occurred in 5.7% of patients in the 90 mg group and 7.6% of patients in the 90⟶180 mg group. One patient (0.9%) in the 90 mg group experienced Grade 2 bradycardia. Monitor heart rate and blood pressure during treatment with ALUNBRIG. Monitor patients more frequently if concomitant use of drug known to cause bradycardia cannot be avoided. For symptomatic bradycardia, withhold ALUNBRIG and review concomitant medications for those known to cause bradycardia. If a concomitant medication known to cause bradycardia is identified and discontinued or dose adjusted, resume ALUNBRIG at the same dose following resolution of symptomatic bradycardia; otherwise, reduce the dose of ALUNBRIG following resolution of symptomatic bradycardia. Discontinue ALUNBRIG for life-threatening bradycardia if no contributing concomitant medication is identified.

Please see additional Important Safety Information on the following page, and full Prescribing Information.

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IMPORTANT SAFETY INFORMATION (continued)

Visual Disturbance

In ALTA 1L, Grade 1 or 2 adverse reactions leading to visual disturbance, including blurred vision, photophobia, photopsia, and reduced visual acuity, were reported in 7.4% of patients receiving ALUNBRIG. In ALTA, adverse reactions leading to visual disturbance, including blurred vision, diplopia, and reduced visual acuity, were reported in 7.3% of patients treated with ALUNBRIG in the 90 mg group and 10% of patients in the 90⟶180 mg group. Grade 3 macular edema and cataract occurred in one patient each in the 90⟶180 mg group. Advise patients to report any visual symptoms. Withhold ALUNBRIG and obtain an ophthalmologic evaluation in patients with new or worsening visual symptoms of Grade 2 or greater severity. Upon recovery of Grade 2 or Grade 3 visual disturbances to Grade 1 severity or baseline, resume ALUNBRIG at a reduced dose. Permanently discontinue treatment with ALUNBRIG for Grade 4 visual disturbances.

Creatine Phosphokinase (CPK) Elevation

In ALTA 1L, creatine phosphokinase (CPK) elevation occurred in 81% of patients who received ALUNBRIG. The incidence of Grade 3 or 4 CPK elevation was 24%. Dose reduction for CPK elevation occurred in 15% of patients. In ALTA, CPK elevation occurred in 27% of patients receiving ALUNBRIG in the 90 mg group and 48% of patients in the 90⟶180 mg group. The incidence of Grade 3 to 4 CPK elevation was 2.8% in the 90 mg group and 12% in the 90⟶180 mg group. Dose reduction for CPK elevation occurred in 1.8% of patients in the 90 mg group and 4.5% of patients in the 90⟶180 mg group. Advise patients to report any unexplained muscle pain, tenderness, or weakness. Monitor CPK levels during ALUNBRIG treatment. Withhold ALUNBRIG for Grade 3 or 4 CPK elevation with Grade 2 or higher muscle pain or weakness. Upon resolution or recovery to Grade 1 CPK elevation or baseline, resume ALUNBRIG at the same dose or at a reduced dose per Table 2 of the full Prescribing Information.

Pancreatic Enzyme Elevation

In ALTA 1L, amylase elevation occurred in 52% of patients and Grade 3 or 4 amylase elevation occurred in 6.8% of patients who received ALUNBRIG. Lipase elevations occurred in 59% of patients and Grade 3 or 4 lipase elevation occurred in 17% of patients. In ALTA, amylase elevation occurred in 27% of patients in the 90 mg group and 39% of patients in the 90⟶180 mg group. Lipase elevations occurred in 21% of patients in the 90 mg group and 45% of patients in the 90⟶180 mg group. Grade 3 or 4 amylase elevation occurred in 3.7% of patients in the 90 mg group and 2.7% of patients in the 90⟶180 mg group. Grade 3 or 4 lipase elevation occurred in 4.6% of patients in the 90 mg group and 5.5% of patients in the 90⟶180 mg group. Monitor lipase and amylase during treatment with ALUNBRIG. Withhold ALUNBRIG for Grade 3 or 4 pancreatic enzyme elevation. Upon resolution or recovery to Grade 1 or baseline, resume ALUNBRIG at the same dose or at a reduced dose.

Hepatoxicity

In ALTA 1L, aspartate aminotransferase (AST) elevations occurred in 72% of patients and Grade 3 or 4 AST elevations occurred in 4.5% of patients who received ALUNBRIG. Alanine aminotransferase (ALT) elevations occurred in 52% of patients and Grade 3 or 4 ALT elevations occurred in 5.2% of patients. One patient (0.7%) had a serious adverse reaction of hepatocellular injury. In ALTA, AST elevations occurred in 38% of patients in the 90 mg group and 65% of patients in the 90⟶180 mg group. ALT elevations occurred in 34% of patients in the 90 mg group and 40% of patients in the 90⟶180 mg group. Grade 3 or 4 AST elevations occurred in 0.9% of patients in the 90 mg group and did not occur in any patients in the 90⟶180 mg group. Grade 3 or 4 ALT elevations did not occur in any patients in the 90 mg group and in 2.7% of patients in the 90⟶180 mg group. Monitor AST, ALT and total bilirubin during treatment with ALUNBRIG, especially during the first 3 months. Withhold ALUNBRIG for Grade 3 or 4 hepatic enzyme elevation with bilirubin less than or equal to 2 × ULN. Upon resolution or recovery to Grade 1 or less (less than or equal to 3 × ULN) or to baseline, resume ALUNBRIG at a next lower dose per Table 2 of the full Prescribing Information. Permanently discontinue ALUNBRIG for Grade 2 to 4 hepatic enzyme elevation with concurrent total bilirubin elevation greater than 2 times the ULN in the absence of cholestasis or hemolysis.

Hyperglycemia

In ALTA 1L, 56% of patients who received ALUNBRIG experienced new or worsening hyperglycemia. Grade 3 hyperglycemia, based on laboratory assessment of serum fasting glucose levels, occurred in 7.5% of patients. In ALTA, 43% of patients who received ALUNBRIG experienced new or worsening hyperglycemia. Grade 3 hyperglycemia, based on laboratory assessment of serum fasting glucose levels, occurred in 3.7% of patients. Two of 20 (10%) patients with diabetes or glucose intolerance at baseline required initiation of insulin while receiving ALUNBRIG. Assess fasting serum glucose prior to initiation of ALUNBRIG and monitor periodically thereafter. Initiate or optimize anti-hyperglycemic medications as needed. If adequate hyperglycemic control cannot be achieved with optimal medical management, withhold ALUNBRIG until adequate hyperglycemic control is achieved and consider reducing the dose of ALUNBRIG dosage per Table 1 of the full Prescribing Information or permanently discontinuing ALUNBRIG.

Photosensitivity

In ALTA 1L, 3.7% of patients who received ALUNBRIG experienced photosensitivity, with 0.7% of patients experiencing Grade 3 to 4 reactions. In ALTA, 0.9% of patients who received ALUNBRIG in the 90 mg group and 0.9% of patients in the 90⟶180 mg group experienced photosensitivity.

Grade 3 to 4 photosensitivity was not reported in patients in the 90 mg group or in the 90⟶180 mg group. Advise patients to limit sun exposure while taking ALUNBRIG, and for at least 5 days after discontinuation of treatment. Advise patients, when outdoors, to wear a hat and protective clothing, and use a broad-spectrum Ultraviolet A (UVA)/ Ultraviolet B (UVB) sunscreen and lip balm (SPF ≥30) to help protect against sunburn. Based on the severity, withhold ALUNBRIG, then resume at the same dose, or reduce the dose, or permanently discontinue.

Embryo-Fetal Toxicity

Based on its mechanism of action and findings in animals, ALUNBRIG can cause fetal harm when administered to pregnant women. There are no clinical data on the use of ALUNBRIG in pregnant women. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ALUNBRIG and for at least 4 months following the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for at least 3 months after the last dose of ALUNBRIG.

ADVERSE REACTIONS

The most common adverse reactions (≥25%) with ALUNBRIG were diarrhea, fatigue, nausea, rash, cough, myalgia, headache, hypertension, vomiting, and dyspnea.

DRUG INTERACTIONS

CYP3A Inhibitors: Avoid coadministration of ALUNBRIG with strong or moderate CYP3A inhibitors. If coadministration of a strong or moderate CYP3A inhibitor is unavoidable, reduce the dose of ALUNBRIG.

CYP3A Inducers: Avoid coadministration of ALUNBRIG with strong or moderate CYP3A inducers. If coadministration of a moderate CYP3A inducer is unavoidable, increase the dose of ALUNBRIG.

USE IN SPECIFIC POPULATIONS

Females and Males of Reproductive Potential

Verify pregnancy status in females of reproductive potential prior to initiating ALUNBRIG. Advise females of reproductive potential to use effective contraception during treatment with ALUNBRIG and for at least 4 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with ALUNBRIG and for at least 3 months after the final dose. ALUNBRIG may cause reduced fertility in males.

Lactation: Advise not to breastfeed.

Hepatic Impairment: Reduce the dose of ALUNBRIG for patients with severe hepatic impairment.

Renal Impairment: Reduce the dose of ALUNBRIG for patients with severe renal impairment.

To report SUSPECTED ADVERSE REACTIONS, contact Takeda Pharmaceuticals U.S.A., Inc. at 1-844-217-6468 or the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Please see full Prescribing Information.