STARTING PATIENTS WITH THE

ALUNBRIG® (brigatinib) SMART™ FREE TRIAL PROGRAM

The ALUNBRIG SMART Free Trial Program is a simple program **offering a 1-month free trial** to determine whether ALUNBRIG is appropriate for your next patient with **ALK+ mNSCLC**.

Enroll patients for a free[a] trial with ALUNBRIG.

Enroll your patients online at **ALUNBRIGSMART.com/eConsent** or by scanning the QR code.

To enroll your patients via fax, please see inside for details.

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.

[a]Free for the first month of treatment. Please note that if you and your patient decide that ALUNBRIG is right for them, a new prescription will need to be written to continue treatment beyond the 1-month free trial period. Please see page 2 for full eligibility details and requirements.

ALK, anaplastic lymphoma kinase; FDA, Food and Drug Administration; mNSCLC, metastatic non-small cell lung cancer.

Please see Important Safety Information on pages 4-5 and accompanying full Prescribing Information in pocket.

Please see page 3 for information about Takeda Oncology Here2Assist®.

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

INITIATING PATIENTS WITH THE ALUNBRIG (brigatinib) SMART™ FREE TRIAL PROGRAM

To get your eligible[a] patient started:

Visit **ALUNBRIGSMART.com/eConsent** to complete the online program request form, or scan the QR code

OR

Visit **ALUNBRIGSMART.com** to download and complete the program request form, and fax it to **1-857-465-7247**

AND

Your patient will receive a **1-month free trial of ALUNBRIG** sent directly to their home

Please do not remit prescriptions to Takeda Oncology Here2Assist®.

Eligible patients must:

- Be newly diagnosed with ALK+ mNSCLC as detected by an FDA-approved test
- **Be treatment-naive to ALUNBRIG**
- **Not have a prior prescription for ALUNBRIG**
- Have no prior enrollment history in the ALUNBRIG SMART Free Trial Program

There is no obligation to continue the use of ALUNBRIG after the free trial has been completed. A prescription will need to be written for continued use of ALUNBRIG after the free trial program.

After you write a prescription, **Takeda Oncology Here2Assist** can help identify financial assistance programs that may be able to help your patients with the cost of their Takeda Oncology treatment. **Please see page 3 for more information.**

[a]Review patient eligibility criteria—certain restrictions apply. Patients must be physically present in the US. Patients from territories of the US, such as Puerto Rico, are ineligible. Patients are not required to be legal citizens of the US to qualify for the ALUNBRIG SMART Free Trial Program. Participating patients must be under the care of a physician licensed in the US. Patients must provide a shipping address based in the US.

After participating in the ALUNBRIG SMART Free Trial Program,* patients can receive additional financial assistance from

Takeda Oncology Here2Assist®

Committed to supporting your patients

Takeda Oncology Here2Assist is a comprehensive support program committed to helping your patients navigate coverage requirements, identify available financial assistance, and connect with helpful resources throughout their Takeda Oncology treatment.

As our programs continuously evolve to adapt to your patients' needs, Takeda Oncology Here2Assist:

- Works with your patients' insurance company to help get your patient started on their medication
- Identifies available financial assistance that may be right for your patients
- May help eligible patients get started on treatment in the event of an insurance delay
- Identifies specialty pharmacies to help fill and ship your patients' prescriptions appropriately
- Conducts regular follow-up calls to patients
- Sends text message status updates and reminders to patients[†]

Your patients can enroll online by visiting **Here2Assist.com** or by scanning the QR code. You will be notified once they enroll.

Patients can also download and print the enrollment form and bring it to your office.

*Please do not enroll patients in the Here2Assist program while applying for the ALUNBRIG SMART Free Trial program.

[†]Patients will need to enroll in the texting program to receive text messages.

Please see Important Safety Information on pages 4-5 and accompanying full Prescribing Information in pocket.

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

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 for Grade 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.

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.

WARNINGS AND PRECAUTIONS (continued)

Hepatotoxicity

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 patients 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 accompanying full Prescribing Information in pocket.

Please see page 3 for information about Takeda Oncology Here2Assist®.

NEXT TIME YOU SEE A PATIENT WITH ALK+ mNSCLC

START THEM ON ALUNBRIG (brigatinib) WITH THE ALUNBRIG SMART™ FREE TRIAL PROGRAM

Enroll patients before prescribing ALUNBRIG to make their first month of therapy free.

Order the ALUNBRIG Initiation Pack when enrolling in the ALUNBRIG SMART Free Trial Program.

The **ALUNBRIG Initiation Pack** contains the first month's supply of the recommended dosage.

- 1 bottle of 90-mg tablets (7 count)
- 1 bottle of 180-mg tablets (23 count)

To order the Initiation Pack, please check "Initiation Pack" under section 4 on page 1 of the ALUNBRIG SMART Program Request Form

Dosing and administration with ALUNBRIG[1]

- Administer ALUNBRIG until disease progression or unacceptable toxicity
- If ALUNBRIG is interrupted for 14 days or longer for reasons other than adverse reactions, resume treatment at 90 mg once daily for 7 days before increasing to the previously tolerated dose
- ALUNBRIG may be taken with or without food. Instruct patients to swallow tablets whole. Do not crush or chew tablets
- Inform patients to avoid grapefruit or grapefruit juice while taking ALUNBRIG
- If a dose of ALUNBRIG is missed or vomiting occurs after taking a dose, do not administer an additional dose. Instruct patients to take the next dose of ALUNBRIG at the scheduled time

Please see Important Safety Information on pages 4-5 and accompanying full Prescribing Information in pocket.

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Reference: 1. Alunbrig. Prescribing information. Takeda Pharmaceuticals America, Inc; 2022.

Takeda | ONCOLOGY

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