



NSCLC PATIENTS START STRONG with AUGTYRO

As a clinical pharmacist, you can help your patients stay on AUGTYRO, a next-generation TKI for *ROS1*+ NSCLC.¹⁻⁴

NATIONAL COMPREHENSIVE CANCER NETWORK® (NCCN®) RECOMMENDED⁵

Repotrectinib (AUGTYRO) is recommended as an NCCN category 2A preferred **first-line** treatment option for patients with *ROS1*+ NSCLC⁵

AUGTYRO is indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer (NSCLC).¹

*Durable response is based on objective response rate and median duration of response for AUGTYRO.

NSCLC=non-small cell lung cancer; ROS1=proto-oncogene C-Ros1, receptor tyrosine kinase; TKI=tyrosine kinase inhibitor.

IMPORTANT SAFETY INFORMATION

Warnings & Precautions

Central Nervous System Adverse Reactions

 Among the 426 patients who received AUGTYRO in Study TRIDENT-1, a broad spectrum of central nervous system (CNS) adverse reactions including dizziness, ataxia, and cognitive disorders occurred in 77% of patients with Grade 3 or 4 events occurring in 4.5%.

TKI-NAÏVE POPULATION

AUGTYRO can offer a strong start in ROS1+ NSCLC

Primary endpoint



~80% ORR^{1,6*†}

79% ORR (n=56/71; 95% CI: 68, 88; 6% CR, 73% PR).[‡] Median follow-up for ORR data: 18.1 months.⁶

Secondary endpoint



icORR seen in 7/8 patients^{1†}

With measurable CNS metastasis at baseline.§ Median follow-up for icORR data: 18.1 months.6

*Durable response is based on objective response rate and median duration of response for AUGTYRO.

¹Data from the TKI-naïve cohort of the pivotal TRIDENT-1 study, a Phase 1/2 multicenter, single-arm, open-label, multicohort clinical trial of AUGTYRO (160 mg orally once daily for 14 days, then increased to 160 mg twice daily until disease progression or unacceptable toxicity) in adult patients with locally advanced or metastatic *ROS1*+ NSCLC. The major efficacy outcome measures were ORR and DOR (assessed by BICR per RECIST v1.1). Efficacy population included patients who received at least 1 dose of AUGTYRO.¹ †CR, n=52/71.^{1,6}

§Intracranial response according to modified RECIST v1.1 was assessed by BICR. Among 71 patients in the TKI-naïve cohort, 8 had measurable CNS metastases at baseline (as assessed by BICR).^{1,6}

IMPORTANT SAFETY INFORMATION (CONT'D)

Central Nervous System Adverse Reactions (cont'd)

• Dizziness, including vertigo, occurred in 65%; Grade 3 dizziness occurred in 2.8% of patients. The median time to onset was 7 days (1 day to 1.4 years). Dose interruption was required in 9% of patients, and 11% required dose reduction of AUGTYRO due to dizziness.

TKI-NAÏVE POPULATION

AUGTYRO: Defining durability* can make a difference



BICR=blinded independent central review; CNS=central nervous system; CR=complete response; DOR=duration of response; icORR=intracranial objective response rate; mDOR=median duration of response; NE=not evaluable, endpoint not yet reached; NSCLC=non-small cell lung cancer; ORR=objective response rate; PR=partial response; RECIST=Response Evaluation Criteria In Solid Tumors; ROS1=proto-oncogene C-Ros1, receptor tyrosine kinase; TKI=tyrosine kinase inhibitor.

IMPORTANT SAFETY INFORMATION (CONT'D)

Central Nervous System Adverse Reactions (cont'd)

Ataxia, including gait disturbance and balance disorder, occurred in 28% of patients; Grade 3 ataxia occurred in 0.5%. The median time to onset was 15 days (1 day to 1.4 years). Dose interruption was required in 5% of patients, 8% required dose reduction and one patient (0.2%) permanently discontinued AUGTYRO due to ataxia.



Adverse reaction profile with AUGTYRO in the TRIDENT-1 study¹

- The pooled safety population included 426 patients who were exposed to AUGTYRO¹
- Serious adverse reactions occurred in 35% of patients who received AUGTYRO. Serious adverse reactions in ≥2% of patients included pneumonia (6.3%), dyspnea (3.1%), pleural effusion (2.8%), and hypoxia (2.6%). Fatal adverse reactions were reported in 3.5% of patients who received AUGTYRO, including pneumonia, pneumonia aspiration, cardiac arrest, sudden cardiac death, cardiac failure, hypoxia, dyspnea, respiratory failure, tremor, and disseminated intravascular coagulation¹



7% of patients permanently discontinued AUGTYR01



As a clinical pharmacist, you play a key role in helping patients manage adverse reactions.

IMPORTANT SAFETY INFORMATION (CONT'D)

Central Nervous System Adverse Reactions (cont'd)

Cognitive impairment, including memory impairment and disturbance in attention, occurred in 25% of patients. Cognitive impairment included memory impairment (15%), disturbance in attention (12%), and confusional state (2%); Grade 3 cognitive impairment occurred in 0.9% of patients. The median time to onset of cognitive disorders was 37 days (1 day to 1.4 years). Dose interruption was required in 2% of patients, 2.1% required dose reduction and 0.5% permanently discontinued AUGTYRO due to cognitive adverse reactions.

Adverse Reaction [†]	AUGTYRO (N=426)	
(≥10%) in patients taking AUGTYRO	All Grades, %	Grade 3 or 4, %
Nervous system disorders		
Dizziness ^a	65	2.8
Dysgeusia ^b	54	0
Peripheral neuropathy ^c	49	1.4
Ataxiad	28	0.5
Cognitive impairment ^e	25	0.9
Headache ^f	19	0
Gastrointestinal disorders		
Constipation	38	0.2
Nausea	20	0.7
Diarrhea	14	0.7
Vomiting	12	1.2
Respiratory, thoracic, and mediastinal disorders		
Dyspnea ^g	30	6
Cough ^h	18	0.2
Pneumonia ⁱ	11	6
General disorders		
Fatigue ^j	30	1.2
Edema ^k	15	0.5
Decreased appetite	11	0.2
Musculoskeletal and connective tissue disorders		
Muscular weakness	20	2
Myalgia ⁱ	13	0.7
Metabolism and nutritional		
Increased weight	16	3
Eye disorders		
Vision disorders ^m	12	0.5

^{*}Based on NCI CTCAE v4.03

alncludes terms dizziness, vertigo, dizziness postural, dizziness exertional, vertigo positional. blncludes terms dysgeusia, ageusia, anosmia, hypogeusia. ^cIncludes terms neuralgia, neuropathy peripheral, peripheral sensory neuropathy, dysesthesia, peripheral motor neuropathy, polyneuropathy, paresthesia, hypoesthesia, hyperesthesia. dIncludes terms ataxia, gait disturbance, balance disorder, cerebellar ataxia and coordination abnormal. Includes terms memory impairment, disturbance in attention, cognitive disorder, confusional state, amnesia, attention deficit hyperactivity disorder, delirium, altered state of consciousness, aphasia, delusion, depressed level of consciousness, hallucination, mental status changes, neurological decompensation. flncludes terms headache, migraine, tension headache. Includes terms dyspnea and dyspnea exertional. Includes terms productive cough, cough, and upper-airway cough syndrome. Includes terms pneumonia, pneumonia aspiration, lower respiratory tract infection, pneumonia viral, pneumonia bacterial, lower respiratory tract infection bacterial, pneumonia klebsiella. Includes terms fatique and asthenia. kIncludes terms generalized edema, periorbital edema, localized edema, face edema, edema peripheral, edema, eye edema, scrotal edema. ^IIncludes terms myalgia, myositis, musculoskeletal discomfort, musculoskeletal pain. mIncludes terms vision blurred, dry eye, visual impairment, visual field defect, cataract, conjunctivitis, eye pain, photophobia, photosensitivity reaction, visual acuity reduced, vitreous floaters, blepharospasm, color blindness, diplopia, eve hematoma, eve swelling, eyelid disorder, eyelid injury, eyelids pruritus, glaucoma, night blindness, ophthalmic herpes zoster.

CTCAE=Common Terminology Criteria for Adverse Events; NCI=National Cancer Institute.



Getting your patients started with AUGTYRO

 Prior to initiating AUGTYRO, discontinue strong and moderate CYP3A inhibitors for 3 to 5 elimination half-lives of the CYP3A inhibitor¹

RECOMMENDED TESTING FOR INITIATION AND FOLLOW-UP

Test	Prior to Initiation	Initiation/Monitoring
Liver function tests including bilirubin	•	Every 2 weeks for first month; monthly thereafter and as clinically indicated ¹
Uric acid level	•	Periodic monitoring during treatment ¹
Serum CPK levels	N/A	Every 2 weeks for first month; periodic monitoring as clinically indicated thereafter ¹
Interstitial lung disease/pneumonitis	N/A	Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis ¹

IMPORTANT SAFETY INFORMATION (CONT'D)

Central Nervous System Adverse Reactions (cont'd)

 Mood disorders occurred in 6% of patients. Mood disorders occurring in >1% of patients included anxiety (2.6%); Grade 4 mood disorders (mania) occurred in 0.2% of patients. Dose interruption was required in 0.2% of patients and 0.2% required a dose reduction due to mood disorders.

Recommended oral dose of AUGTYRO1*

Days 1-14	Day 15 Onward
160 mg QD	160 mg BID
(4x 40-mg capsules, or a single	(4x 40-mg capsules, or a single
160-mg capsule, once daily)	160-mg capsule, twice daily)

^{*}Until disease progression or unacceptable toxicity.





AUGTYRO can be taken with or without food11



Capsules should be swallowed whole at approximately the same time every day as prescribed¹



Contents of the capsule should not be opened, crushed, chewed, or dissolved¹



If a dose is missed or if a patient vomits at any time after taking a dose, instruct patients to skip the dose and resume at the regularly scheduled time. Two doses should not be taken at the same time¹

[†]Advise patients not to drink grapefruit juice or eat grapefruit while taking AUGTYRO. [†] CPK=creatine phosphokinase; CYP3A=cytochrome P4503A; ILD=interstitial lung disease.

IMPORTANT SAFETY INFORMATION (CONT'D)

Central Nervous System Adverse Reactions (cont'd)

• Sleep disorders including insomnia and hypersomnia occurred in 18% of patients. Sleep disorders observed in >1% of patients were somnolence (9%), insomnia (6%) and hypersomnia (1.6%). Dose interruption was required in 0.7% of patients, and 0.2% required a dose reduction due to sleep disorders.



Recommended dose reductions with AUGTYRO¹

Adjustable dosing allows for dose modification if needed for adverse reactions*

Recommended Dose Reductions for Adverse Reactions				
Dose	Dose Reduction			
	First	Second		
160 mg Once Daily	120 mg Once Daily	80 mg Once Daily		
160 mg Twice Daily	120 mg Twice Daily	80 mg Twice Daily		



A prescription for 40-mg capsules is required for dose reductions

As a clinical pharmacist, you play a key role in helping patients manage adverse reactions by checking in with them periodically

IMPORTANT SAFETY INFORMATION (CONT'D)

Central Nervous System Adverse Reactions (cont'd)

- The incidences of CNS adverse reactions reported were similar in patients with and without CNS metastases.
- Advise patients not to drive or use machines if they are experiencing CNS adverse reactions. Withhold and then resume at same or reduced dose upon improvement, or permanently discontinue AUGTYRO based on severity.

Recommended dosage modifications for select ARs

Central nervous system effects¹

- If intolerable Grade 2, withhold AUGTYRO until ≤Grade 1 or baseline, then resume at same or reduced dose, as clinically appropriate
- If Grade 4, permanently discontinue AUGTYRO

ILD/pneumonitis

 For any grade, withhold AUGTYRO if ILD/pneumonitis is suspected and permanently discontinue if confirmed

Hepatotoxicity¹

- If Grade 3, withhold AUGTYRO until
 ≤Grade 1 or baseline. Resume at
 same dose if resolution occurs
 within 4 weeks, or at reduced dose
 for recurrent Grade 3 events that
 resolve within 4 weeks
- If Grade 4, withhold AUGTYRO until
 ≤Grade 1 or baseline. Resume at
 reduced dose if resolution occurs
 within 4 weeks. Permanently
 discontinue if AR does not resolve
 within 4 weeks or if it recurs
- If ALT or AST >3 times the ULN with concurrent total bilirubin
 >1.5 times ULN (in absence of cholestasis or hemolysis), permanently discontinue AUGTYRO

Dizziness¹

- If intolerable Grade 2, withhold AUGTYRO until ≤Grade1 or baseline, then resume at same or reduced dose, as clinically appropriate

CPK elevation

- If CPK elevation >5 times ULN, withhold AUGTYRO until baseline or ≤2.5 times ULN, then resume at same dose
- If CPK elevation >10 times ULN or second occurrence of CPK elevation of >5 times ULN, withhold AUGTYRO until baseline or ≤2.5 times ULN, then resume at reduced dose

Hyperuricemia¹

 If Grade 3 or 4, withhold AUGTYRO until improvement of signs or symptoms, then resume AUGTYRO at same or reduced dose

Other clinically relevant ARs1

 If intolerable Grade 2, Grade 3, or Grade 4 AR, withhold AUGTYRO until ≤Grade 1 or baseline, then resume at same or reduced dose if resolution occurs within 4 weeks.
 Permanently discontinue if AR does not resolve within 4 weeks, or if recurrent Grade 4

ALT=alanine aminotransferase; AR=adverse reaction; AST=aspartate aminotransferase; CPK=creatine phosphokinase; CTCAE=Common Terminology Criteria for Adverse Events; ILD=interstitial lung disease; ULN=upper limit of normal.



^{*}Graded per CTCAE v4.03.

IMPORTANT SAFETY INFORMATION (CONT'D)

Interstitial Lung Disease (ILD)/Pneumonitis

- Among the 426 patients treated with AUGTYRO, ILD/pneumonitis (pneumonitis [2.8%] and ILD [0.2%]) occurred in 3.1%; Grade 3 ILD/pneumonitis occurred in 1.2%. The median time to onset was 45 days (19 days to 0.9 years). Dose interruption was required in 1.4% of patients, 0.5% required dose reduction, and 1.1% permanently discontinued AUGTYRO due to ILD/pneumonitis.
- Monitor patients for new or worsening pulmonary symptoms indicative
 of ILD/pneumonitis. Immediately withhold AUGTYRO in patients with
 suspected ILD/pneumonitis and permanently discontinue AUGTYRO if ILD/
 pneumonitis is confirmed.

Hepatotoxicity

- Among the 426 patients treated with AUGTYRO, increased alanine transaminase (ALT) occurred in 38%, increased aspartate aminotransferase (AST) occurred in 41%, including Grade 3 or 4 increased ALT in 3.3% and increased AST in 2.9%. The median time to onset of increased ALT or AST was 15 days (range: 1 day to 1.9 years). Increased ALT or AST leading to dose interruptions or reductions occurred in 2.8% and 1.2% of patients, respectively. Hyperbilirubinemia leading to dose interruptions occurred in 0.5%.
- Monitor liver function tests, including ALT, AST and bilirubin, every 2 weeks
 during the first month of treatment, then monthly thereafter and then as
 clinically indicated. Withhold and then resume at same or reduced dose upon
 improvement or permanently discontinue AUGTYRO based on the severity.

Myalgia with Creatine Phosphokinase (CPK) Elevation

- AUGTYRO can cause myalgia with or without creatine phosphokinase (CPK) elevation. Among the 426 patients treated with AUGTYRO, myalgia occurred in 13% of patients, with Grade 3 in 0.7%. Median time to onset of myalgia was 19 days (range: 1 day to 2 years). Concurrent increased CPK within a 7-day window was observed in 3.7% of patients. AUGTYRO was interrupted in one patient with myalgia and concurrent CPK elevation.
- Advise patients to report any unexplained muscle pain, tenderness, or weakness. Monitor serum CPK levels during AUGTYRO treatment and monitor CPK levels every 2 weeks during the first month of treatment and as needed in patients reporting unexplained muscle pain, tenderness, or weakness. Initiate supportive care as clinically indicated. Based on severity, withhold and then resume AUGTYRO at same or reduced dose upon improvement.

Hyperuricemia

 Among the 426 patients treated with AUGTYRO, 21 patients (5%) experienced hyperuricemia reported as an adverse reaction, 0.7% experienced Grade 3 or 4 hyperuricemia. One patient without pre-existing gout required urate-lowering medication.

Hyperuricemia (cont'd)

• Monitor serum uric acid levels prior to initiating AUGTYRO and periodically during treatment. Initiate treatment with urate-lowering medications as clinically indicated. Withhold and then resume at same or reduced dose upon improvement, or permanently discontinue AUGTYRO based on severity.

Skeletal Fractures

- Among 426 adult patients who received AUGTYRO, fractures occurred in 2.3%. Fractures involved the ribs (0.5%), feet (0.5%), spine (0.2%), acetabulum (0.2%), sternum (0.2%), and ankles (0.2%). Some fractures occurred at sites of disease and prior radiation therapy. The median time to fracture was 71 days (range: 31 days to 1.4 years). AUGTYRO was interrupted in 0.3% of patients.
- Of 26 evaluable patients in an ongoing open-label study in pediatric patients, fractures occurred in one 12-year-old patient (ankle/foot) and one 10-year-old patient (stress fracture). AUGTYRO was interrupted in both patients. AUGTYRO is not approved for use in pediatric patients less than 12 years of age.
- Promptly evaluate patients with signs or symptoms (e.g., pain, changes in mobility, deformity) of fractures. There are no data on the effects of AUGTYRO on healing of known fractures and risk of future fractures.

Embryo-Fetal Toxicity

- Based on literature reports in humans with congenital mutations leading to changes in tropomyosin receptor tyrosine kinase (TRK) signaling, findings from animal studies, and its mechanism of action, AUGTYRO can cause fetal harm when administered to a pregnant woman.
- Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective non-hormonal contraception during treatment with AUGTYRO and for 2 months following the last dose, since AUGTYRO can render some hormonal contraceptives ineffective.
- Advise male patients with female partners of reproductive potential to use
 effective contraception during treatment with AUGTYRO and for 4 months
 after the last dose.

Adverse Reactions

• The safety of AUGTYRO was evaluated in 426 patients in TRIDENT-1. The most common adverse reactions (≥20%) were dizziness, dysgeusia, peripheral neuropathy, constipation, dyspnea, fatigue, ataxia, cognitive impairment, muscular weakness, and nausea.



SUPPORT

IMPORTANT SAFETY INFORMATION (CONT'D)

Drug Interactions Effects of Other Drugs on AUGTYRO

Strong and Moderate CYP3A Inhibitors

Avoid concomitant use with strong or moderate CYP3A inhibitors.
 Concomitant use of AUGTYRO with a strong or a moderate CYP3A inhibitor
 may increase repotrectinib exposure, which may increase the incidence
 and severity of adverse reactions of AUGTYRO. Discontinue CYP3A
 inhibitors for 3 to 5 elimination half-lives of the CYP3A inhibitor prior to
 initiating AUGTYRO.

P-gp Inhibitors

Avoid concomitant use with P-gp inhibitors. Concomitant use of AUGTYRO with a P-gp inhibitor may increase repotrectinib exposure, which may increase the incidence and severity of adverse reactions of AUGTYRO.

Strong and Moderate CYP3A Inducers

Avoid concomitant use with strong or moderate CYP3A inducers.
 Concomitant use of AUGTYRO with a strong or moderate CYP3A inducer may decrease repotrectinib plasma concentrations, which may decrease efficacy of AUGTYRO.

Effects of AUGTYRO on other Drugs

Certain CYP3A4 Substrates

- Avoid concomitant use unless otherwise recommended in the Prescribing Information for CYP3A substrates, where minimal concentration changes can cause reduced efficacy. If concomitant use is unavoidable, increase the CYP3A4 substrate dosage in accordance with approved product labeling.
- Repotrectinib is a CYP3A4 inducer. Concomitant use of repotrectinib decreases the concentration of CYP3A4 substrates, which can reduce the efficacy of these substrates.

Contraceptives

- Repotrectinib is a CYP3A4 inducer, which can decrease progestin or estrogen exposure to an extent that could reduce the effectiveness of hormonal contraceptives.
- Avoid concomitant use of AUGTYRO with hormonal contraceptives.
 Advise females of childbearing potential to use an effective nonhormonal contraceptive.

Please see full <u>U.S. Prescribing Information</u>.

References: 1. AUGTYRO [package insert]. Princeton, NJ. Bristol-Myers Squibb Company. 2. Yun MR, Kim DH, Kim SY, et al. Repotrectinib exhibits potent antitumor activity in treatmentnaïve and solvent-front-mutant ROS1-rearranged non-small cell lung cancer. Clin Cancer Res. 2020;26(13):3287-3295. 3. Murray BW, Rogers É, Zhai D, et al. Molecular characteristics of repotrectinib that enable potent inhibition of TRK fusion proteins and resistant mutations. Mol Cancer Ther. 2021;20(12):2446-2456. 4. Drilon A, Ou SI, Cho BC, et al. Repotrectinib (TPX-0005) is a next-generation ROS1/TRK/ALK inhibitor that potently inhibits ROS1/TRK/ALK solvent-front mutations. Cancer Discov. 2018;8(10):1227-1236. 5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.11.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed November 5, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. 6. Cho BC, Lin JJ, Camidge DR, et al. Pivotal topline data from the phase 1/2 TRIDENT-1 trial of repotrectinib in patients with ROS1+ advanced non-small cell lung cancer (NSCLC). Eur J Cancer. 2022;174 (suppl1):S1-S2. 7. Cho BC, Camidge DR, Lin JJ, et al. Repotrectinib in patients with ROS1 fusion-positive non-small cell lung cancer: update from the pivotal phase 1/2 TRIDENT-1 trial. Presented at: 2023 World Conference on Lung Cancer; September 9-12, 2023; Singapore.



At Bristol Myers Squibb, We Provide Support With Purpose



The BMS Access Support® program is focused on helping patients access their prescribed medicine

Patients are the reason behind what we do. BMS Access Support® is dedicated to helping patients access their prescribed BMS medications. When patients are prescribed AUGTYRO™ (repotrectinib) and enroll in BMS Access Support, they will have access to:





Financial Support*



Educational Resources



Co-Pay Assistance Program*

Eligible, commercially-insured patients may pay as little as \$0 per one-month supply (subject to an out-of-pocket maximum)



Free Trial Offer (FTO)*

A 29-day supply of AUGTYRO may be available for newly prescribed patients



Bridge Program*

In the event of a coverage delay or denial, commercially-insured patients may be eligible for a bridge program for up to 2 months

*Restrictions apply. Please see full Terms & Conditions, including complete eligibility requirements.

We're here for you. Coverage assistance, educational resources, and financial support options may be available through **BMS Access Support®**



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Find resources and enrollment information at www.BMSAccessSupport.com



Schedule a meeting with an Access & Reimbursement Manager via the BMS Access Support website

Support for your patients



Support throughout a patient's journey.

A complimentary program for patients that includes helpful resources and information about support and advocacy groups, and provides access to a personal care counselor for patients who have been prescribed AUGTYRO.

Eligible patients may enroll in the program by visiting AUGTYRO.com.

Click here to learn more about support for your ROS1+ NSCLC patients taking AUGTYRO



[†]The accurate completion and submission of reimbursement and coverage-related documentation to the patient's insurance plan is the responsibility of the provider and patient. Bristol Myers Squibb and its agents cannot guarantee coverage for any medication or treatment.



DURABILITY* CAN START HERE

AUGTYRO | A standard of care in ROS1+ NSCLC

In the TKI-naïve population of the pivotal TRIDENT-1 study

Primary endpoint

~80% ORR^{1,6*†}

79% ORR(n=56/71; 95% CI: 68, 88; 6% CR, 73% PR)[‡]

Median follow-up for ORR data: 18.1 months.6

Secondary endpoint

~3-YR mDOR^{1,7*†}

34-month mDOR (95% CI: 25.6, NE; range: 1.4+, 42.4+ months)

Median follow-up for DOR data: 24.0 months.7

Secondary endpoint

icorr seen in 7/8 patients¹†

with measurable CNS metastasis at baseline[§]

Median follow-up for icORR data: 18.1 months.6

*Durable response is based on objective response rate and median duration of response for AUGTYRO.¹
¹Data from the TKI-naïve cohort of the pivotal TRIDENT-1 study.¹
‡CR. n=4/71: PR. n=52/71.¹6

§Intracranial response according to modified RECIST v1.1 was assessed by BICR. Among 71 patients in the TKI-naïve cohort, 8 had measurable CNS metastases at baseline (as assessed by BICR). BICR=blinded independent central review; CNS=central nervous system; CR=complete response; DOR=duration of response; icORR=intracranial objective response rate; mDOR=median duration of response; NE=not evaluable, endpoint not yet reached; ORR=objective response rate; PR=partial response; RECIST=Response Evaluation Criteria In Solid Tumors; TKI=tyrosine kinase inhibitor.

SELECT IMPORTANT SAFETY INFORMATION

SUMMARY OF WARNINGS AND PRECAUTIONS

 AUGTYRO is associated with the following warnings and precautions: central nervous system (CNS) adverse reactions, interstitial lung disease (ILD)/ pneumonitis, hepatotoxicity, myalgia with creatine phosphokinase (CPK) elevation, hyperuricemia, skeletal fractures, and embryo-fetal toxicity.

Please see additional Important Safety Information throughout and click here for <u>U.S. Full Prescribing Information</u> for AUGTYRO.

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