# NOW APPROVED



**GAVRETO<sup>™</sup>**—the only once-daily targeted **RET therapy** for patients with RET+ metastatic NSCLC or advanced thyroid cancers.<sup>1</sup>

## For more information, visit: **GAVRETOhcp.com**

NSCLC=non-small cell lung cancer; RET=rearranged during transfection.

#### INDICATIONS

GAVRETO<sup>™</sup> (pralsetinib) is indicated for the treatment of:

- Adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC)
   as detected by an FDA approved test
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy
- Adult and pediatric patients 12 years of age and older with RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)

These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

#### SELECT SAFETY INFORMATION

**Interstitial Lung Disease (ILD)/Pneumonitis** occurred in 10% of patients who received GAVRETO, including 2.7% with Grade 3/4, and 0.5% with fatal reactions. Monitor for pulmonary symptoms indicative of ILD/pneumonitis. Withhold GAVRETO and promptly investigate for ILD in any patient who presents with acute or worsening of respiratory symptoms (e.g., dyspnea, cough, and fever). Withhold, reduce dose or permanently discontinue GAVRETO based on severity of confirmed ILD.

Please see additional Select Safety Information throughout, and click here to see the full <u>Prescribing Information</u> for GAVRETO.

### In preclinical studies, pralsetinib was designed for potent and selective inhibition of RET

### **ARROW** study design in the NSCLC population

Efficacy and safety with GAVRETO (400 mg orally once daily) was evaluated in patients with RET fusion+ mNSCLC in the ARROW study, a phase 1/2, nonrandomized, open-label, single-arm, multicohort, multicenter clinical trial. Patients with asymptomatic central nervous system metastases, including patients with stable or decreasing steroid use within 2 weeks prior to study entry, were enrolled.

### Demographic characteristics in the NSCLC population at baseline<sup>1,2</sup>

	Treatment-naïve patients (n=27)	Previously platinum-treated patients (n=87)
Median age	65 years (30-87)	60 years (28-85)
Gender	52% female 48% male	49% female 51% male
Race/ethnicity	59% White, 33% Asian, 4% Hispanic/Latino	53% White, 35% Asian, 6% Hispanic/Latino
ECOG status	0-1: 96% 2: 4%	0-1: 94% 2: 6%
RET fusion partner	70% KIF5B 11% CCDC6	75% KIF5B 17% CCDC6
History of or current CNS metastases at baseline	37%	43%
Prior therapy	Per protocol, patients were not eligible for platinum-based chemotherapy based on investigator assessment <sup>2</sup>	45% PD-1/PD-L1 inhibitor, 25% prior kinase inhibitors
Patient identification	67% NGS • 41% tumor samples • 22% blood or plasma • 4% unknown 33% FISH	<ul> <li>77% NGS</li> <li>45% tumor samples</li> <li>26% blood or plasma</li> <li>6% unknown</li> <li>21% FISH</li> <li>2% other</li> </ul>

ECOG=Eastern Cooperative Oncology Group; FISH=fluorescence in situ hybridization; mNSCLC=metastatic non-small cell lung cancer;

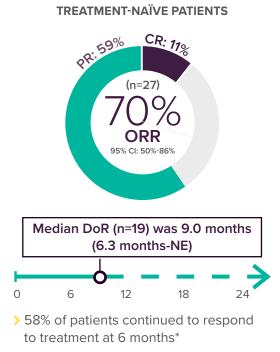
NGS=next generation sequencing; PD-1/PD-L1=programmed cell death 1/programmed death ligand 1; RECIST=Response Evaluation Criteria in Solid Tumors.

### SELECT SAFETY INFORMATION

**Hypertension** occurred in 29% of patients, including Grade 3 hypertension in 14% of patients. Overall, 7% had their dose interrupted and 3.2% had their dose reduced for hypertension. Treatment-emergent hypertension was most commonly managed with anti-hypertension medications. Do not initiate GAVRETO in patients with uncontrolled hypertension. Optimize blood pressure prior to initiating GAVRETO. Monitor blood pressure after 1 week, at least monthly thereafter and as clinically indicated. Initiate or adjust anti-hypertensive therapy as appropriate. Withhold, reduce dose, or permanently discontinue GAVRETO based on the severity.

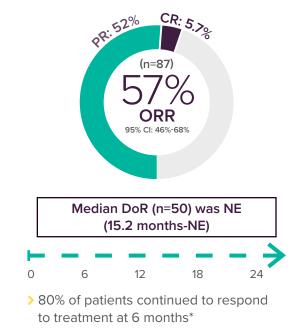
### Efficacy results with GAVRETO<sup>1,2</sup>

The major efficacy outcome measures were overall response rate (ORR) and duration of response (DoR), as assessed by a blinded independent central review (BICR) according to RECIST v1.1.



> Median time to first response was 1.9 months (range: 1.4-5.6 months)<sup>2</sup>

#### PREVIOUSLY PLATINUM-TREATED PATIENTS



Median time to first response was 1.8 months (range: 1.3-9.1 months)<sup>2</sup>

# GAVRETO demonstrated consistent response across previously platinum-treated subgroups<sup>1</sup>



### CNS ACTIVITY

Brain metastases at baseline (n=8)<sup>+</sup>: DoR at 6 months: 75%



of patients with measurable disease had a response

### PRIOR PD-1/PD-L1 INHIBITOR | Exploratory analysis



Median DoR was not reached (95% CI: 11.3-NE)

\*Calculated using the proportion of responders with an observed duration of response at least 6 months or greater.

<sup>†</sup>No patients received radiation therapy (RT) to the brain within 2 months prior to study entry. Cl=confidence interval; CNS=central nervous system; CR=complete response; NE=not estimable; PR=partial response.



Safety of GAVRETO was evaluated in 438 patients with RET-altered tumors, including RET+ mNSCLC (n=220) and RET-altered thyroid cancer (n=138) in ARROW<sup>1</sup>

### Safety of GAVRETO in 438 patients with RET-altered tumors

- > The most common adverse reactions (≥25%) were constipation, hypertension, fatigue, musculoskeletal pain and diarrhea.
- > The most common Grade 3-4 laboratory abnormalities (≥2%) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased phosphate, decreased calcium (corrected), decreased sodium, increased aspartate aminotransferase (AST), increased alanine aminotransferase (ALT), decreased platelets, and increased alkaline phosphatase.
- In 34 patients with RET-altered solid tumors, no large mean increase in QTc (>20 ms) was detected in the study.

### Safety of GAVRETO in RET+ mNSCLC

## Adverse reactions (≥15%) in RET fusion-positive mNSCLC patients (n=220) who received GAVRETO in ARROW

	GAVRE	GAVRETO N=220	
Adverse Reactions	Grades 1-4 (%)	Grades 3-4 (%)	
General			
Fatigue*	35	2.3**	
Pyrexia	20	0	
Edema <sup>+</sup>	20	0	
Gastrointestinal			
Constipation	35	1**	
Diarrhea‡	24	3.2**	
Dry mouth	16	0	
Musculoskeletal Disorders			
Musculoskeletal pain <sup>§</sup>	32	0	
Vascular			
Hypertension	28	14**	
Respiratory, thoracic, and mediastinal			
Cough <sup>1</sup>	23	0.5**	
Infections			
Pneumonia <sup>#</sup>	17	8	

\*Fatigue includes fatigue, asthenia.

<sup>+</sup>Edema includes edema peripheral, face edema, periorbital edema, eyelid edema, edema generalized, swelling.

<sup>‡</sup>Diarrhea includes diarrhea, colitis, enteritis.

<sup>§</sup>Musculoskeletal pain includes back pain, myalgia, arthralgia, pain in extremity, musculoskeletal pain, neck pain, musculoskeletal chest pain, bone pain, musculoskeletal stiffness, arthritis, spinal pain.

"Hypertension includes hypertension, blood pressure increased.

<sup>1</sup>Cough includes cough, productive cough, upper-airway cough syndrome.

<sup>#</sup>Pneumonia includes pneumonia, atypical pneumonia, lung infection, pneumocystis jirovecii pneumonia, pneumonia bacterial, pneumonia cytomegaloviral, pneumonia haemophilus, pneumonia influenza, pneumonia streptococcal.

\*\*Only includes a Grade 3 adverse reaction.

### GAVRETO was generally well tolerated in mNSCLC<sup>1</sup>

15% of patients permanently discontinued GAVRETO due to any adverse reaction;6.4% discontinued due to adverse reactions considered treatment-related by the trial investigator<sup>1,2</sup>

Adverse reactions resulting in permanent discontinuation included pneumonitis (1.8%), pneumonia (1.8%), and sepsis (1%).

# 36% Dose reductions due to adverse reactions in GAVRETO-treated patients

### 60% Dosage interruptions due to an adverse reaction in GAVRETO-treated patients

Adverse reactions requiring dosage reductions in  $\geq 2\%$  of patients included neutropenia, anemia, pneumonitis, neutrophil count decreased, fatigue, hypertension, pneumonia, and leukopenia.

Adverse reactions requiring dosage interruption in ≥2% of patients included neutropenia, pneumonitis, anemia, hypertension, pneumonia, pyrexia, increased aspartate aminotransferase (AST), increased blood creatine phosphokinase, fatigue, leukopenia, thrombocytopenia, vomiting, increased alanine aminotransferase (ALT), sepsis, and dyspnea.

## Select laboratory abnormalities (≥20%) worsening from baseline in patients who received GAVRETO in ARROW

	GAVRETO N=220	
Laboratory Abnormality*	Grades 1-4 (%)	Grades 3-4 (%)
Chemistry		
Increased AST	74	2.3
Increased ALT	49	2.3
Increased alkaline phosphatase	42	1.8
Decreased calcium (corrected)	39	1.8
Decreased albumin	36	0
Decreased phosphate	35	11
Increased creatinine	33	0.5
Decreased sodium	29	7
Increased potassium	26	0.9
Hematology		
Decreased neutrophils	61	16
Decreased hemoglobin	58	9
Decreased lymphocytes	56	19
Decreased platelets	27	3.2

\*Denominator for each laboratory parameter is based on the number of patients with a baseline and post-treatment laboratory value available, which ranged from 216 to 218 patients.

Clinically relevant laboratory abnormalities <20% of patients who received GAVRETO included increased phosphate (10%).



### ARROW study design in thyroid cancer population

Efficacy and safety with GAVRETO (400 mg orally once daily) was evaluated in patients with advanced or metastatic RET-mutant+ MTC and advanced or metastatic RET fusion+ thyroid cancer in the ARROW study, a phase 1/2, nonrandomized, open-label, single-arm, multicohort, multicenter clinical trial.

### Demographic characteristics in the advanced thyroid cancer population at baseline

	MTC: cabozantinib and vandetanib-naïve patients* (n=29)	MTC: previously cabozantinib and/or vandetanib treated patients <sup>†</sup> (n=55)	RET fusion-positive thyroid cancer patients <sup>‡</sup> (n=9)
Median age	61 years (19-81)	59 years (25-83)	61 years (46-74)
Gender	28% female 72% male	31% female 69% male	33% female 67% male
Race/ethnicity	76% White 17% Asian 3.4% Hispanic/Latino	78% White 5% Asian 5% Hispanic/Latino	78% White 22% Asian 11% Hispanic/Latino
ECOG status	0-1: 100%	0-1: 95% 2: 5%	0-1: 100%
History of CNS metastases at baseline	14%	7%	56%
Patient identification	90% NGS • 52% tumor sample • 35% plasma • 3.4% blood 10% PCR	73% NGS • 55% tumor sample • 18% plasma 26% PCR 2% other	89% NGS 11% FISH

\*97% of patients had metastatic disease. 28% had received up to 3 lines of prior systemic therapy (including 10% PD-1/PD-L1 inhibitors, 10% radioactive iodine, 3.4% kinase inhibitors).

<sup>+</sup>Patients had received a median of 2 prior therapies (range 1-7). The primary mutations in RET-mutant MTC previously treated with

cabozantinib or vandetanib are described in Table 10 of the Full Prescribing Information for GAVRETO.

\*All patients had papillary thyroid cancer. All patients had metastatic disease. Patients had received a median of 2 prior therapies (range 1-8). Prior systemic treatments included prior radioactive iodine (100%) and prior sorafenib and/or lenvatinib (56%).

### SELECT SAFETY INFORMATION

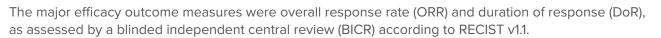
**Hepatotoxicity:** Serious hepatic adverse reactions occurred in 2.1% of patients treated with GAVRETO. Increased aspartate aminotransferase (AST) occurred in 69% of patients, including Grade 3/4 in 5% and increased alanine aminotransferase (ALT) occurred in 46% of patients, including Grade 3/4 in 6%. The median time to first onset for increased AST was 15 days (range: 5 days to 1.5 years) and increased ALT was 22 days (range: 7 days to 1.7 years). Monitor AST and ALT prior to initiating GAVRETO, every 2 weeks during the first 3 months, then monthly thereafter and as clinically indicated. Withhold, reduce dose or permanently discontinue GAVRETO based on severity.

Grade  $\geq$  3 **hemorrhagic events** occurred in 2.5% of patients treated with GAVRETO including one patient with a fatal hemorrhagic event. Permanently discontinue GAVRETO in patients with severe or life-threatening hemorrhage.

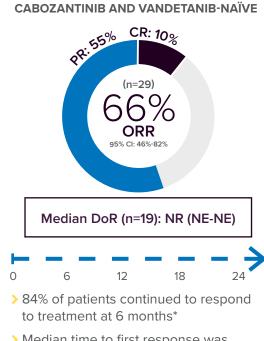
**Tumor Lysis Syndrome (TLS):** Cases of TLS have been reported in patients with medullary thyroid carcinoma receiving GAVRETO. Patients may be at risk of TLS if they have rapidly growing tumors, a high tumor burden, renal dysfunction, or dehydration. Closely monitor patients at risk, consider appropriate prophylaxis including hydration, and treat as clinically indicated.

Please see additional Select Safety Information throughout, and click here to see the full <u>Prescribing Information</u> for GAVRETO.

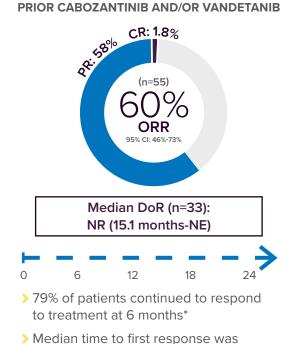
# GAVRETO demonstrated robust and durable response regardless of prior therapy in advanced thyroid cancers<sup>1</sup>



### Efficacy results with GAVRETO in advanced or metastatic RET-mutant MTC

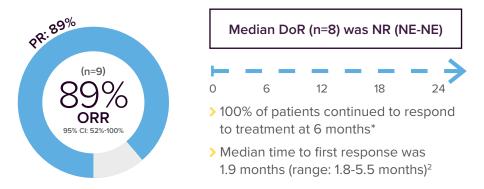


Median time to first response was 3.7 months (range: 1.7-11.1 months)<sup>2</sup>



3.7 months (range: 1.8-12.9 months)<sup>2</sup>

### Efficacy results with GAVRETO in advanced or metastatic RET fusion+ thyroid cancer



\*Calculated using the proportion of responders with an observed duration of response at least 6 months or greater.

### SELECT SAFETY INFORMATION

**Impaired wound healing** can occur in patients who receive drugs that inhibit the vascular endothelial growth factor (VEGF) signaling pathway. Therefore, GAVRETO has the potential to adversely affect wound healing. Withhold GAVRETO for at least 5 days prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of GAVRETO after resolution of wound healing complications has not been established.

Please see additional Select Safety Information throughout, and click here to see the full <u>Prescribing Information</u> for GAVRETO.



### Adverse reactions (≥15%) in RET-altered thyroid cancer patients who received **GAVRETO** in **ARROW**

	GAVRETO (N=138)	
Adverse Reactions	Grades 1-4 (%)	Grades 3-4 (%)
Musculoskeletal		
Musculoskeletal pain*	42	0.7##
Gastrointestinal		
Constipation	41	0.7**
Diarrhea <sup>+</sup>	34	5##
Abdominal pain‡	17	0.7**
Dry mouth	17	0
Stomatitis <sup>§</sup>	17	0.7##
Nausea	17	0.7**
Vascular		
Hypertension	40	21##
General		
Fatigue <sup>®</sup>	38	6##
Edema <sup>1</sup>	29	0
Pyrexia	22	2.2##
Nervous system		
Headache <sup>#</sup>	24	0
Peripheral neuropathy **	20	0
Dizziness <sup>++</sup>	19	0.7**
Dysgeusia <sup>‡‡</sup>	17	0
Respiratory		
Cough <sup>§§</sup>	27	1.4##
Dyspnea <sup>Ⅲ</sup>	22	2.2##
Skin and subcutaneous		
Rash <sup>11</sup>	24	0
Metabolism and nutrition		
Decreased appetite	15	0

\*Musculoskeletal Pain includes arthralgia, arthritis, back pain, bone pain, musculoskeletal chest pain, musculoskeletal pain, musculoskeletal stiffness, myalgia, neck pain, non-cardiac chest pain, pain in extremity, spinal pain.

Diarrhea includes colitis, diarrhea. Abdominal pain includes abdominal discomfort, abdominal pain, abdominal pain upper, abdominal tenderness, epigastric discomfort.

<sup>§</sup>Stomatitis includes mucosal inflammation, stomatitis, tongue ulceration.

"Fatigue includes asthenia, fatigue. "Edema includes eyelid edema, face edema, edema, edema peripheral, periorbital edema. #Headache includes headache, migraine

\*\*Peripheral neuropathy includes dysaesthesia, hyperaesthesia, hypoaesthesia, neuralgia, neuropathy peripheral, paraesthesia, peripheral sensory neuropathy, polyneuropathy.

<sup>+</sup>Dizziness includes dizziness, dizziness postural, vertigo.

<sup>®</sup>Dysgeusia includes ageusia, dysgeusia. Cough includes cough, productive cough, upper-airway cough syndrome. Dyspnea includes dyspnea, dyspnea exertional.

"Rash includes dermatitis, dermatitis acneiform, eczema, palmar-plantar, erythrodysaesthesia syndrome, rash, rash erythematous, rash macular, rash maculo-papular, rash papular, rash pustular. ##Only includes a Grade 3 adverse reaction.

Clinically relevant adverse reactions in <15% of patients who received GAVRETO included tumor lysis syndrome and increased creatine phosphokinase.

# GAVRETO was generally well tolerated in RET-altered thyroid cancer<sup>1</sup>

**9%** of patients permanently discontinued GAVRETO due to any adverse reaction; 3.6% discontinued due to adverse reactions considered treatment-related by the trial investigator<sup>1,2</sup>

Adverse reactions resulting in permanent discontinuation which occurred in >1 patient included fatigue, pneumonia and anemia.

#### Dose reductions due to adverse 44% reactions in GAVRETO-treated patients



# 67% Dosage interruptions due to an adverse reaction in GAVRETO-treated patients

Adverse reactions requiring dosage reductions in  $\geq 2\%$  of patients included neutropenia, anemia, hypertension, increased blood creatine phosphokinase, decreased lymphocyte count, pneumonitis, fatigue and thrombocytopenia.

Adverse reactions requiring dosage interruption in  $\ge 2\%$  of patients included neutropenia, hypertension, diarrhea, fatique, pneumonitis, anemia, increased blood creatine phosphokinase, pneumonia, urinary tract infection, musculoskeletal pain, vomiting, pyrexia, increased AST, dyspnea, hypocalcemia, cough, thrombocytopenia, abdominal pain, increased blood creatinine, dizziness, headache, decreased lymphocyte count, stomatitis, and syncope.

### Select laboratory abnormalities (≥20%) worsening from baseline in patients who received GAVRETO in ARROW

Labovatow (Abrovnality*	GAVRETO (N=138)	
Laboratory Abnormality*	Grades 1-4 (%)	Grades 3-4 (%)
Chemistry		
Decreased calcium (corrected)	70	9
Increased aspartate aminotransferase (AST)	69	4.3
Increased alanine aminotransferase (ALT)	43	3.6
Increased creatinine	41	0
Decreased albumin	41	1.5
Decreased sodium	28	2.2
Decreased phosphate	28	8
Decreased magnesium	27	0.7
Increased potassium	26	1.4
Increased bilirubin	24	1.4
Increased alkaline phosphatase	22	1.4
Hematology		
Decreased lymphocytes	67	27
Decreased hemoglobin	63	13
Decreased neutrophils	59	16
Decreased platelets	31	2.9

\*Denominator for each laboratory parameter is based on the number of patients with a baseline and post-treatment laboratory value available, which ranged from 135 to 138 patients.

Clinically relevant laboratory abnormalities in patients who received GAVRETO included increased phosphate (40%).



### GAVRETO: the only once-daily RET inhibitor<sup>1</sup>



### Recommended starting dose: 400 mg once daily



Four 100-mg capsules Bottle and capsules

are not actual size



Patients should take GAVRETO on an empty stomach (no food intake for at least 2 hours before and at least 1 hour after taking GAVRETO).

Continue treatment until disease progression or until unacceptable toxicity.

If a dose of GAVRETO is missed, it can be taken as soon as possible on the same day. Resume the regular daily dose schedule for GAVRETO the next day. Advise patients not to take an additional dose if vomiting occurs after taking GAVRETO but to continue with the next dose as scheduled.

Select patients for treatment with GAVRETO based on the presence of a RET gene fusion (NSCLC or thyroid cancer) or RET gene mutation (MTC).

### **Recommended dosage reductions for adverse reactions**



Second reduction: 200 mg once daily



100 mg once daily

Permanently discontinue GAVRETO in patients who are unable to tolerate 100 mg taken orally once daily.

### **Drug Interactions**

- Strong CYP3A inhibitors: Avoid coadministration.
- Combined P-gp and Strong CYP3A inhibitors: Avoid coadministration. If coadministration cannot be avoided, reduce the dose of GAVRETO as shown in Table 3 of the Prescribing Information.
- Strong CYP3A inducers: Avoid coadministration. If coadministration cannot be avoided, increase the dose of GAVRETO as shown in Section 2.5 of the Prescribing Information.

GAVRETO is available in 100-mg capsules, giving you the opportunity to modify dosage based on individual patient needs

### SELECT SAFETY INFORMATION

Based on findings from animal studies and its mechanism of action, GAVRETO 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 GAVRETO and for 2 weeks after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with GAVRETO and for 1 week after the final dose. Advise women not to breastfeed during treatment with GAVRETO and for 1 week after the final dose.

Please see additional Select Safety Information throughout, and click here to see the full <u>Prescribing Information</u> for GAVRETO.



## A support program for your patients

Personalized support and financial assistance for your patients taking GAVRETO

YourBlueprint<sup>™</sup> is a patient support program designed with your patients' care in mind. YourBlueprint assists patients throughout many aspects of treatment by providing:



Financial assistance

options

Temporary treatment

programs



Reimbursement support

TO ENROLL YOUR PATIENTS, VISIT US ONLINE AT

YourBlueprint.com/HCP

Call 1-888-BLUPRNT (1-888-258-7768) Monday-Friday 8AM-8PM Eastern Time (ET)

## **Co-Pay Assistance Program**



This program helps eligible, commercially insured patients reduce their out-of-pocket costs (co-pay, co-insurance, or deductible) to as little as \$0. For more information, see the full Terms and Conditions at YourBlueprint.com/HCP.





### Consider GAVRETO for your RET+ mNSCLC and advanced thyroid cancer patients<sup>1</sup>



The only once-daily RET inhibitor that selectively inhibits RET in mNSCLC, advanced or metastatic MTC, and advanced or metastatic thyroid cancer<sup>1</sup>



GAVRETO demonstrated meaningful responses across multiple subgroups, regardless of prior therapy or history of CNS metastases at baseline<sup>1</sup>



GAVRETO was generally well tolerated:

- In mNSCLC, 15% of patients permanently discontinued GAVRETO due to any adverse reaction; 6.4% discontinued due to adverse reactions considered treatment-related by the trial investigator<sup>1,2</sup>
- In advanced thyroid cancers, 9% of patients permanently discontinued GAVRETO due to any adverse reaction; 3.6% discontinued due to adverse reactions considered treatment-related by the trial investigator<sup>1,2</sup>

### SELECT SAFETY INFORMATION

Common adverse reactions (≥25%) were constipation, hypertension, fatigue, musculoskeletal pain and diarrhea. Common Grade 3-4 laboratory abnormalities (≥2%) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased phosphate, decreased calcium (corrected), decreased sodium, increased aspartate aminotransferase (AST), increased alanine aminotransferase (ALT), decreased platelets and increased alkaline phosphatase.

Avoid coadministration of GAVRETO with strong CYP3A inhibitors or combined P-gp and strong CYP3A inhibitors. If coadministration cannot be avoided, reduce the GAVRETO dose. Avoid coadministration of GAVRETO with strong CYP3A inducers. If coadministration cannot be avoided, increase the GAVRETO dose.

## Please see additional Select Safety Information throughout, and click here to see the full <u>Prescribing Information</u> for GAVRETO.

References: 1. GAVRETO<sup>™</sup> (pralsetinib). Prescribing Information. Blueprint Medicines Corporation; Cambridge, MA. December 2020.
 2. Data on file. Blueprint Medicines Corporation. Cambridge, MA 2020.

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