

# GAVRETO<sup>®</sup>

pralsetinib | 100mg capsules



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

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

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

## 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 [Prescribing Information](#) for GAVRETO.



# GAVRETO was studied in both treatment-naïve and previously platinum-treated NSCLC patients<sup>1</sup>

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.

mNSCLC=metastatic non-small cell lung cancer.

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

	Treatment-naïve patients (n=27)	Previously platinum-treated patients (n=87)
<b>Median age</b>	65 years (30-87)	60 years (28-85)
<b>Gender</b>	52% female 48% male	49% female 51% male
<b>Race/ethnicity</b>	59% White, 33% Asian, 4% Hispanic/Latino	53% White, 35% Asian, 6% Hispanic/Latino
<b>ECOG status</b>	0-1: 96% 2: 4%	0-1: 94% 2: 6%
<b>RET fusion partner</b>	70% KIF5B 11% CCDC6	75% KIF5B 17% CCDC6
<b>History of or current CNS metastases at baseline</b>	37%	43%
<b>Prior therapy</b>	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
<b>Patient identification</b>	67% NGS <ul style="list-style-type: none"> <li>• 41% tumor samples</li> <li>• 22% blood or plasma</li> <li>• 4% unknown</li> </ul> 33% FISH	77% NGS <ul style="list-style-type: none"> <li>• 45% tumor samples</li> <li>• 26% blood or plasma</li> <li>• 6% unknown</li> </ul> 21% FISH 2% other

ECOG=Eastern Cooperative Oncology Group; FISH=fluorescence in situ hybridization; 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.

Please see additional Select Safety Information throughout, and click here to see the full [Prescribing Information](#) for GAVRETO.



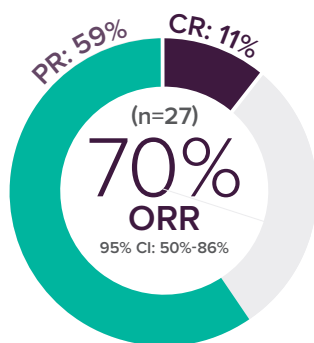
# GAVRETO demonstrated robust and durable response with or without prior therapy in NSCLC<sup>1</sup>



## 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.

### TREATMENT-NAÏVE PATIENTS

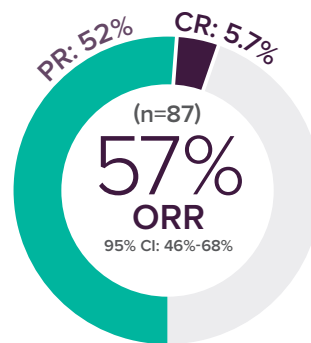


Median DoR (n=19) was 9.0 months (6.3 months-NE)



- > 58% of patients continued to respond to treatment at 6 months\*
- > Median time to first response was 1.9 months (range: 1.4-5.6 months)<sup>2</sup>

### PREVIOUSLY PLATINUM-TREATED PATIENTS



Median DoR (n=50) was NE (15.2 months-NE)



- > 80% of patients continued to respond to treatment at 6 months\*
- > Median time to first response was 1.8 months (range: 1.3-9.1 months)<sup>2</sup>

CI=confidence interval; CR=complete response; NE=not estimable; PR=partial response.

## 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%

**50%** of patients with measurable disease had a response  
2 had CR

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

(n=39):  
**59% ORR**  
(95% CI: 42%-74%)

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.

CNS=central nervous system.

# 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

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

<sup>||</sup>Hypertension includes hypertension, blood pressure increased.

<sup>¶</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  $\geq 2\%$  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 ( $\geq 20\%$ ) worsening from baseline in patients who received GAVRETO in ARROW

Laboratory Abnormality*	GAVRETO N=220	
	Grades 1-4 (%)	Grades 3-4 (%)
<b>Chemistry</b>		
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
<b>Hematology</b>		
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%).



# GAVRETO was studied in RET-altered thyroid cancer patients<sup>1</sup>

## 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. All patients must have had a non-resectable RET-altered solid tumor or MTC per local assessment of tumor tissue and/or blood. All patients must also have had an Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0-1.<sup>1,3</sup>

MTC=medullary thyroid cancer.

## 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† (n=55)	RET fusion-positive thyroid cancer patients‡ (n=9)
<b>Median age</b>	61 years (19-81)	59 years (25-83)	61 years (46-74)
<b>Gender</b>	28% female 72% male	31% female 69% male	33% female 67% male
<b>Race/ethnicity</b>	76% White 17% Asian 3.4% Hispanic/Latino	78% White 5% Asian 5% Hispanic/Latino	78% White 22% Asian 11% Hispanic/Latino
<b>ECOG status</b>	0-1: 100%	0-1: 95% 2: 5%	0-1: 100%
<b>History of CNS metastases at baseline</b>	14%	7%	56%
<b>Patient identification</b>	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).

†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 ≥ 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 [Prescribing Information](#) for GAVRETO.



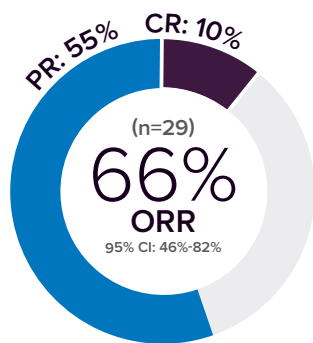
# GAVRETO demonstrated robust and durable response in advanced thyroid cancers<sup>1</sup>



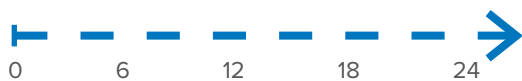
The major efficacy outcome measures were overall response rate (ORR) and duration of response (DoR), as assessed by a blinded independent central review (BICR) according to RECIST v1.1.

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

### CABOZANTINIB AND VANDETANIB-NAÏVE

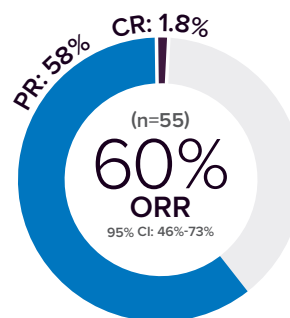


Median DoR (n=19): NR (NE-NE)

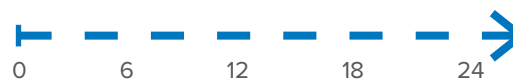


- > 84% of patients continued to respond to treatment at 6 months\*
- > Median time to first response was 3.7 months (range: 1.7-11.1 months)<sup>2</sup>

### PRIOR CABOZANTINIB AND/OR VANDETANIB

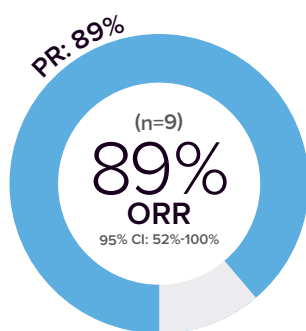


Median DoR (n=33): NR (15.1 months-NE)



- > 79% of patients continued to respond to treatment at 6 months\*
- > Median time to first response was 3.7 months (range: 1.8-12.9 months)<sup>2</sup>

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



Median DoR (n=8) was NR (NE-NE)



- > 100% of patients continued to respond to treatment at 6 months\*
- > Median time to first response was 1.9 months (range: 1.8-5.5 months)<sup>2</sup>

\*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 [Prescribing Information](#) for GAVRETO.



# Safety of GAVRETO in 138 patients with RET-altered thyroid cancer

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

Adverse Reactions	GAVRETO (N=138)	
	Grades 1-4 (%)	Grades 3-4 (%)
<b>Musculoskeletal</b>		
Musculoskeletal pain*	42	0.7##
<b>Gastrointestinal</b>		
Constipation	41	0.7##
Diarrhea†	34	5##
Abdominal pain‡	17	0.7##
Dry mouth	17	0
Stomatitis§	17	0.7##
Nausea	17	0.7##
<b>Vascular</b>		
Hypertension	40	21##
<b>General</b>		
Fatigue	38	6##
Edema¹	29	0
Pyrexia	22	2.2##
<b>Nervous system</b>		
Headache#	24	0
Peripheral neuropathy **	20	0
Dizziness++	19	0.7##
Dysgeusia##	17	0
<b>Respiratory</b>		
Cough§§	27	1.4##
Dyspnea	22	2.2##
<b>Skin and subcutaneous</b>		
Rash¶¶	24	0
<b>Metabolism and nutrition</b>		
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.

§Stomatitis includes mucosal inflammation, stomatitis, tongue ulceration.

||Fatigue includes asthenia, fatigue.

¹Edema 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.

++Dizziness includes dizziness, dizziness postural, vertigo.

##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, erythroderma 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.

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

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

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

Adverse reactions requiring dosage interruption in ≥2% of patients included neutropenia, hypertension, diarrhea, fatigue, 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

Laboratory Abnormality*	GAVRETO (N=138)	
	Grades 1-4 (%)	Grades 3-4 (%)
<b>Chemistry</b>		
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
<b>Hematology</b>		
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



**First reduction:**  
300 mg once daily



**Second reduction:**  
200 mg once daily



**Final reduction:**  
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 [Prescribing Information](#) for GAVRETO.



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

**RET<sup>+</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 was studied across multiple subgroups, including those with a history of CNS metastases at baseline<sup>1</sup>



▶ 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>

Visit [GAVRETOhcp.com](http://GAVRETOhcp.com)  
to learn more or sign up for updates.

### SELECT SAFETY INFORMATION

Common adverse reactions ( $\geq 25\%$ ) were constipation, hypertension, fatigue, musculoskeletal pain and diarrhea. Common Grade 3-4 laboratory abnormalities ( $\geq 2\%$ ) 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 [Prescribing Information for GAVRETO](#).

**References:** 1. GAVRETO® (pralsetinib). Prescribing Information. Blueprint Medicines Corporation; Cambridge, MA. December 2020. 2. Data on file. Blueprint Medicines Corporation. Cambridge, MA 2020. 3. Phase 1/2 study of the highly-selective RET inhibitor, pralsetinib (BLU-667), in patients with thyroid cancer, non-small cell lung cancer, and other advanced solid tumors (ARROW). <https://clinicaltrials.gov/ct2/show/NCT03037385>. Accessed April 20, 2021.

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